Submitter : **Dr. Barry Mirtsching** **Date: 04/11/2005**

Organization : **Center for Oncology Research & Treatment**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Issue Identifier: Competitive Acquisition Areas

A key issue relating to Competitive Acquisition Areas is the requirement that CAP vendors have arrangements in place sufficient to permit shipment ?at least 5 days each week for competitively biddable drugs and biologicals . . . and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract.? (See also 42 CFR 141.914(f)(2)). We appreciate CMS?s request for comments both on ?how to define timely delivery for routine and emergency drug shipments? and on the ?feasibility of providing same day deliveries for orders received for emergency situations? (70 Fed. Reg. 10745,10760 (March 4, 2005)).

I believe that the proposed timelines for routine and emergency delivery are inadequate and that vendors must be required to make routine deliveries anywhere in their service area within 24-hours of a practice?s submission of a new prescription 7 days a week. I base this recommendation on three principle considerations. First, it is not unusual for oncology practices to operate 6 and 7 days a week to meet their patients? needs. Second, it is estimated that approximately one-third of treatment plans must be modified on the day of treatment due to changes in a patient?s health status. Third, the unavailability of drugs needed on the day of treatment would pose a significant burden on patients who would have to return another day for treatment. This burden can be particularly severe in rural areas were patients may have to travel long distances to receive cancer care.

CMS has the authority to require that CAP vendors be able to delivery drugs within 24 hours 7 days a week under the statutory language in Social Security Act ?1847B(b)(2)(A)(i)(II). That provision imposes two standards on CAP vendors: the ability to make timely deliveries and the ability to ship at least 5 days each week. I believe that CMS should use its authority to define ?timely delivery? as a 24-hour turn around and 7-day-a-week delivery services. I fear that anything less could jeopardize the ability of cancer care specialists to meet their patients? clinical needs.

I believe CMS should not rely on an expectation that oncologists who choose CAP will continue to maintain an adequate inventory of drugs that can be used to treat Medicare patients in emergencies under the inventory replacement provisions of the CAP rule. CAP is expected to spur growth in commercial payers? mandatory vendor imposition (MVI) programs. As a result, some physicians who elect CAP and continue offering in-office drug administration services may cease to maintain any on-site drug inventories. Even those practices that maintain inventories may limit them for a variety of reasons, including differences in the clinical needs of their Medicare and non-Medicare patient bases.

Finally, I note that neither the changes to 42 CFR 414.902 set forth in the proposed rule nor the text of the existing regulation define the term ?emergency.? It is essential for the definition of emergency to be clearly set forth in the final rule and not left to the discretion of each CAP vendor or to the discretion of local carriers tasked with adjudicating practices? claims for drug administration services. Moreover, the definition should turn on the treating physician?s clinical judgment that patient health would suffer from delay in treatment, not on the CAP vendor?s or the local carrier?s remote assessment of the situation.

In closing, I respectfully urge CMS to implement the ?timely delivery? requirement established by MMA as requiring CAP vendors to be able to deliver ordered drugs within 24 hours, 7 days a week.

Submitter : **Dr. myron bednar** **Date: 04/11/2005**

Organization : **Dr. myron bednar**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

The Medicare Modernization Act(MMA) has had a deleterious effect on the cancer care of medicare recipients. The spirit of the cancer care reform was to more accurately cover the services provided and not pay excessively for the medications. However, MMA has reduced both the coverage of the services provided as well as the drugs. Therefore, many medicare patients have to spend the entire day in the hospital rather than one or two hours in the office. Some patients cannot receive therapy at all.

The Competitve Acquisition Program(CAP) further stresses our resources and does not cover the staff time and energy devoted to using a separate vendor for medicare patients. Changes in therapy could not be made expeditiously. Furthermore, emergency medications such as IVIG for ITP or zometa for hypercalcemia may not be available increasing hospitalizations.

We are not adequately reimbursed for our services including nursing time, patient education, nutrition counseling, social work, mixing of medications, disposal of drugs, specialized tubing/needles, specialized bottles and the list goes on. Therefore, to continue providing high quality care to our medicare patients, the deminstration project needs to continue beyond 2005. A facility fee is needed as provided in other specialty services. Also, more fairly pay for drugs with manufacturers having deadlines for increases and reimbursement reflecting those increases. The CAP program does not improve the situation and only provides more bureaucracy which detracts from cancer care.

Submitter : **Ms. Colleen Lee** **Date: 04/11/2005**

Organization : **US Oncology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Speaking from a Cancer Care individual, the cap can lead to many problems for the patient and should not be inforced.

Submitter : Mr. Keith gregory **Date:** 04/11/2005

Organization : C. Michael Jones, MD PC

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

In its implementation of the Medicare Modernization Act of 2003 (MMA), the Centers for Medicare and Medicaid Services (CMS) has sought to more adequately cover the labor, supply, pharmacy, and other costs incurred in the administration of cancer-fighting drugs. Among the steps taken is the adoption of G codes to cover drug administration services and the creation of a demonstration project for 2005 that provided additional reimbursement.

As a result, 2005 Medicare reimbursement for cancer care services is considerably higher than pre-MMA rates. However, total reimbursement will drop dramatically on January 1, 2006, when the demonstration project is scheduled to end and the drug administration transitional factor will be zeroed out.

It has been calculated that the impact of these changes will translate into a $940 underpayment for drug administration services per Medicare beneficiary. Put another way, 2006 Medicare reimbursement for patient care services will cover only an estimated 50.09% of drug administration costs.

This problem is a key factor in the implementation of the Competitive Acquisition Program (CAP) in 2006. Under CAP, middlemen vendors will furnish drugs to physicians who choose to give up the traditional buy-and-bill model and select the CAP model instead. The vendors will be responsible for billing Medicare for the drugs, and the physicians will receive reimbursement only for drug administration services.

CMS expects CAP to appeal to those physicians ?who do not want to be in the drug procurement and drug coinsurance collection business? [70 Fed. Reg. 10750]. Indeed, statements made by CMS and CAP?s Congressional authors all reinforce the notion that CAP is intended to be an option that physicians may choose to adopt in place of the current buy-and-bill model. According to the MMA Conference Report produced by Congress, ?Conferees intend this choice to be completely voluntary on behalf of the physicians? [H. R. Conf. Rep. No. 108-391, 108th Cong., 1st Sess. 593 (2003)].

And yet, it is possible that neither CMS nor Congress has recognized that the viability of these two choices turns on the adequacy of reimbursement for drug administration services. Unless changes are made, many oncologists will face a loss under the buy-and-bill model, a loss that will be even greater should they opt to participate in CAP. This is because the only reimbursement they will receive under CAP is payment for drug administration services ? which will fall well below the cost of providing drug administration services.

In light of the reimbursement shortfall that looms on January 1, 2006, many cancer care specialists will face a very different choice than the one that Congress intended: continue to offer cancer care services to seniors (under buy-and-bill or CAP) and incur a significant net loss?or discontinue offering chemotherapy services to Medicare beneficiaries altogether. Sadly, both approaches threaten the community cancer care services on which millions of Americans now depend.

Congress has clearly stated its intent that patient access to community cancer care must be preserved because it is the source of convenient, cost-effective care for more than 4-out-of-5 American cancer patients. If CMS intends to abide by this intent, it must take additional steps to align Medicare reimbursement with the cost of drug administration services.

Because the level of needed fee schedule restructuring is significant, CMS may be unable to solve this pending crisis before the 2006 Physician Fee Schedule must be published. As a result, I urge CMS to extend the quality demonstration while it works to match drug administration cost and payments. Otherwise, both the CAP and the ASP models will be doomed to failure and many Medicare cancer patients likely will be forced back to hospitals for chemotherapy.

Submitter : **Ms. Nancy Beegle** **Date: 04/11/2005**

Organization : **Rocky Mountain Cancer Centers**

Category : **Other Health Care Professional**

Issue Areas/Comments

1-15

Contracting Process-Quality and Product Integrity Aspects

This process will increase the cost of care to patients and Medicare. Shipped drugs may have to be wasted because of changes in the patient status. There will be increased storage & waste processing needs at sites utilizing this type of service. Please do not impose this system on patients and providers

Submitter : Linda Vozzella **Date:** 04/11/2005

Organization : US Oncology

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Because the level of needed fee schedule restructuring is significant, CMS may be unable to solve this pending crisis before the 2006 Physician Fee Schedule must be published. As a result, I urge CMS to extend the quality demonstration while it works to match drug administration cost and payments. Otherwise, both the CAP and the ASP models will be doomed to failure and many Medicare cancer patients likely will be forced back to hospitals for chemotherapy.

There is no "Financial Model" whether non-profit or profit driven that can operate under such a business plan. There is no room for expanded services in attending to our Senior Americans nor would private or federal lenders approve loans to providers knowing 40% to 50% of their revenue is constantly faceing a loss.

Submitter : Robert Barczewski **Date:** 04/11/2005

Organization : Washington University Division of Oncology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1325-P-82-Attach-1.DOC

Date: 3/14/05
To: Whom It May Concern
From: Dr. John DiPersio
Chief, Division of Oncology
Subj: "Brown Bagging"

"Brown Bagging" is a term that has been commonly used in recent years to describe any attempt to have a patient's drugs administered by a physician's office without that drug being provided by the physician's office, with the drug paid for by the insurance company or patient to a pharmacy specialty company, not the physician's office. For the reasons outlined below, we have instituted a policy that prohibits this practice in all of our physicians' offices.

Brown bagging presents a problem to our practice on six fronts:

1) Clinical Judgment
2) Legal
3) Liability
4) Administrative Burden
5) Patient Co-Pays
6) Financial

1) Clinical Flexibility/Physician Judgment

The use of brown bagging procedures hinders the physician's ability to make decisions based on the patient's health status on the day the patient arrives for treatment. Quality patient care requires the treatment be delivered the same day the patient is in the office. Poor quality and untimely care is a false economy.

2) Legal

Because our practice has its own licensed Pharmacy on site, the Pharmacy must adhere to all the State and Federal laws concerning drugs, their procurement and distribution, etc. Thus, if an insurance company tries to send a drug to our practice that requires manipulation by the Pharmacy, we cannot accept the product on legal grounds because it has been dispensed by another Pharmacy to the patient as a prescription and not supplied to us by a Missouri licensed distributor or wholesaler.

3) Liability

If a medication arrives in our practice (brought in by patient, shipped from another Pharmacy, etc.) from a source other than our Pharmacy, and the drug requires administration by any of our staff, we would automatically assume some degree of liability if our staff administers the medication. If there is any problem with the medication (even if it comes from another source), we can be held liable for our part in administering the drug. We do not believe that even signed waivers of liability or

responsibility by specialty pharmacies and insurance companies will protect us from a lawsuit in the event of an adverse outcome in a brown bagging situation.

4) Administrative Burden

The practice of insurance companies sending drugs in advance of treatment to physicians' offices is not practical or cost-effective from a daily operational point of view. Informal surveys of oncology physicians' offices have shown that as many as one-third of oncology patients have their treatment changed (i.e., postponed because of blood count problems, admitted to the hospital, different dosing that prescribed due to change in health status, etc.) on the day of their scheduled treatment. These changes result in wasted drugs that are sent by the insurance company and not used, or may require the physician's office to supply drugs from the office stock that day that were not ordered originally. The storage, record-keeping and administrative work required to organize, monitor and sort through these issues is not only an additional cost that is very expensive, there is no reimbursement for these expenses.

5) Patient Co-Pays

Some brown bagging arrangements shift the responsibility for collection of payments to the specialty pharmacy that provides the drugs. Patients in these scenarios with significant co-pay responsibilities often have difficulty making these payments. Most physician offices, including ours, work with these patients and frequently must absorb the costs when patients have no ability to pay. Patients with life-threatening illnesses cannot afford any delays in treatment while administrative issues are addressed by a specialty pharmacy or insurance company that has very limited personal contact with the patient.

6) Financial

Pharmaceuticals are a significant and important source of revenue for our practice to help keep us financially solvent. The revenues generated by pharmaceuticals help us to cover the many costs that oncology practices are not reimbursed for in the current system.

On the surface, brown bagging may seem to be a creative way to reduce healthcare costs. However, further investigation into the issues surrounding this practice reveals many concerns with the hidden costs and potential negative impacts on patient care. These are the reasons we prohibit any form of brown bagging at this time in our offices.

Submitter : Carolyn Kirk **Date:** 04/11/2005

Organization : US Oncology

Category : Individual

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

The design and implementation of a competitive acquisition program for Part B drugs is an enormous undertaking. It is also an undertaking that will move Medicare into largely uncharted waters. That fact alone argues for a cautious approach.

Although CMS has managed two competitive acquisition demonstration projects for certain types of durable medical equipment, prosthetics and supplies (DMEPOS) in limited geographic markets, it has never organized and run a competitive acquisition program on a national or even a regional scale. The Part B drug CAP differs significantly from the DMEPOS demonstrations because of complicated state licensing and regulatory schemes, the criticality of most of the products involved from a beneficiary perspective, the single-source nature of many of the drugs to be furnished, and the necessity for substantial changes in Medicare claims processing systems that go beyond anything required to implement the DMEPOS demonstrations.

With DME, there were numerous established suppliers operating in a largely unregulated state licensure environment. Because participation in the demonstration by Medicare beneficiaries living in the test areas was mandatory, the bidders knew the size of the potential market. The bidders also ran established businesses and clearly understood the cost structures of those businesses. Unlike the situation with single-source drugs that are the standard of care for many cancer patients today, each product category subject to DMEPOS competitive bidding included numerous items under most HCPCS codes subject to the demonstration. Also unlike the situation that will face manufacturers of Part B drugs in 2006, the discounts extended to DMEPOS competitive bidders did not impact Medicare reimbursement for the manufacturer?s product in locations outside the demonstration area. In other words, with DMEPOS, CMS could count on an adequate supply of qualified bidders positioned to put forth bids consistent with required quality and service standards without sacrificing reasonable profitability and jeopardizing solvency. Furthermore, the product categories included in the DMEPOS demonstrations are not generally seen as carrying the same level concern about product integrity or medical errors as do Part B drugs. Therefore, if DMEPOS CAP vendors stinted on quality or service, the likely outcome for beneficiaries was not as potentially significant as if problems develop with the Part B drug CAP.

The GAO issued a final report to Congress assessing the DMEPOS demonstrations in September 2004. In that report, the GAO suggested that CMS consider conducting more competitive bidding demonstrations for items and services not in the original demonstrations prior to the beginning of the MMA-mandated implementation of CAP for DMEPOS.

This suggestion argues for taking a slow approach to the Part B drug CAP. In fact, it appears that CMS may already agree. In its final report on the DMEPOS CAP demonstration projects, CMS observed 'one of the benefits of conducting demonstrations projects is the ability to learn from the demonstration and apply the lessons if the demonstration is adopted on a wider scale.'

Instead of diving into a national CAP involving all Part B drugs used in 'incident to' services, CMS should begin with a regional or national test involving a limited set of drugs that are typically administered by a physician specialty that uses drugs less intensely than oncology. This would allow CMS to refine its application and vendor selection procedures & its quality and service requirements, correct glitches in CAP upgrades to its claims processing systems, work out handling issues stemming from state regulations, assess and adjust for changes in practice expenses attributable to CAP, & complete the work needed to better match the reimbursement rates for drug administration services to actual costs for the various specialties before CAP is implemented more universally.

Competitive Acquisitions Areas

A key issue relating to Competitive Acquisition Areas is the requirement that CAP vendors have arrangements in place sufficient to permit shipment 'at least 5 days each week for competitively biddable drugs and biologicals . . . and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract.' (See also 42 CFR 141.914(f)(2)). We appreciate CMS's request for comments both on 'how to define timely delivery for routine and emergency drug shipments' and on the 'feasibility of providing same day deliveries for orders received for emergency situations' (70 Fed. Reg. 10745,10760 (March 4, 2005)).

I believe that the proposed timelines for routine and emergency delivery are inadequate and that vendors must be required to make routine deliveries anywhere in their service area within 24-hours of a practice's submission of a new prescription 7 days a week. I base this recommendation on three principle considerations. First, it is not unusual for oncology practices to operate 6 and 7 days a week to meet their patients' needs. Second, it is estimated that approximately one-third of treatment plans must be modified on the day of treatment due to changes in a patient's health status. Third, the unavailability of drugs needed on the day of treatment would pose a significant burden on patients who would have to return another day for treatment. This burden can be particularly severe in rural areas were patients may have to travel long distances to receive cancer care.

CMS has the authority to require that CAP vendors be able to delivery drugs within 24 hours 7 days a week under the statutory language in Social Security Act 1847B(b)(2)(A)(i)(II). That provision imposes two standards on CAP vendors: the ability to make timely deliveries and the ability to ship at least 5 days each week. I believe that CMS should use its authority to define 'timely delivery' as a 24-hour turn around and 7-day-a-week delivery services. I fear that anything less could jeopardize the ability of cancer care specialists to meet their patients' clinical needs.

I believe CMS should not rely on an expectation that oncologists who choose CAP will continue to maintain an adequate inventory of drugs that can be used to treat Medicare patients in emergencies under the inventory replacement provisions of the CAP rule. CAP is expected to spur growth in commercial payers' mandatory vendor imposition (MVI) programs. As a result, some physicians who elect CAP and continue offering in-office drug administration services may cease to maintain any on-site drug inventories. Even those practices that maintain inventories may limit them for a variety of reasons, including differences in the clinical needs of their Medicare and non-Medicare patient bases.

Finally, I note that neither the changes to 42 CFR 414.902 set forth in the proposed rule nor the text of the existing regulation define the term 'emergency.' It is

essential for the definition of emergency to be clearly set forth in the final rule and not left to the discretion of each CAP vendor or to the discretion of local carriers tasked with adjudicating practices' claims for drug administration services. Moreover, the definition should turn on the treating physician's clinical judgment that patient health would suffer from delay in treatment, not on the CAP vendor's or the local carrier's remote assessment of the situation.

In closing, I respectfully urge CMS to implement the ?timely delivery? requirement established by MMA as requiring CAP vendors to be able to deliver ordered drugs within 24 hours, 7 days a week.

Cap Bidding Process-Evaluation and Selection

CMS intends to contract only with qualified CAP bidders that submit composite bids with a weighted average price per HCPCS unit that is no greater than 106% of the weighted ASP for the drugs in the category. US Oncology has consistently taken the position that reimbursement at 106% of ASP is inadequate to cover physicians' costs for chemotherapy drugs and for pharmacy management services and other associated expenses, including bad debt, that are currently not considered in the practice expense component of the drug administration G codes.

Just as I believe this level of reimbursement is inadequate for physicians under the buy-and-bill model, so too do I view reimbursement at 106% of ASP to be inadequate under the CAP model. Competition will not cause manufacturers of most single-source drugs to discount their products to CAP vendors or to any other class of buyer that must be considered when Best Price is calculated. And, like physician practices nationwide, bad debt will pose a major financial challenge to CAP vendors.

In addition, CAP vendors will incur significant middleman costs, including administrative, dispensing, shipping, product disposal, and bad debt costs. These costs are borne by physicians practices everyday, but CAP vendors will likely face even greater difficulty collecting due to the time delay between the dates of treatment and payment, as well as their lack of a direct relationship with patients. Beneficiaries who are already contending with deductibles and coinsurance payments not covered by secondary insurance, travel expenses, custodial care expenses, costs associated with changed dietary needs, etc., may place a relatively low priority on paying their CAP vendors.

Just as the absence of personal relationships between beneficiaries and CAP vendors is likely to exacerbate the vendors' bad debt collection problems, I fear it will also exacerbate some vendors' use of overly aggressive collection efforts, including decisions to stop providing drugs for patients who are too far in arrears. The Practicing Physicians Advisory Council has also raised this concern and proposed that CMS address it in the final CAP rule by mandating that vendors advance credit to patients unable to afford their coinsurance payments. CMS should go a step further and ask that the vendors also be required to have in place procedures for assessing indigence and waiving coinsurance when a non-Medicaid-eligible beneficiary's income, assets, and medical expenses meet certain pre-established criteria. Ideally, these procedures should incorporate the assistance of social workers trained to explore all payment options and assistance programs available to the individual.

Unlike the situation with physicians where reimbursement for Part B drugs supplied under the buy-and-bill model is set by statute at 106% of ASP, CMS may have the discretionary authority under Social Security Act 1847B to permit payments to CAP vendors at any level necessary to compensate them fairly and appropriately for their services. It appears that Congress only expected competition under the CAP model to save money on multi-source drug products, not single-source drugs and biologicals.

Pre-defining an unrealistically low reimbursement cap could under-capitalize vendors, resulting in too few qualified bidders, the provision of improper services, and patient harm. Therefore, CMS should either abandon the notion that CAP will save money in the aggregate for Medicare Part B or phase in the program slowly by starting with a small group of drugs or with a specialty that does not use 'incident to' drugs intensively to test the impact of an potentially under-reimbursed CAP model on beneficiary access to care and on the robustness and financial viability of the CAP vendor market.

In either case, one conclusion should be recognized: just as 106% of ASP is too low in the buy-and-bill model, so too is it unsustainable in CAP.

Contracting Process-Quality and Product Integrity Aspects

In an effort to ensure the stability of CAP, MMA directs CMS to require CAP vendors to meet standards for quality, service, financial performance and solvency that include appropriate procedures for the resolution of physician complaints and grievances. Unfortunately, the statute offers few specifics regarding these standards, and the proposed rule does not define all of the standards to which the vendors will be held. As it has done in the DMEPOS Supplier manuals, CMS should issue CAP guidance that defines measurable quality, service, financial performance and solvency standards.

With respect to Quality and Service Standards, I believe CMS should focus on standards related to shipment errors (e.g., wrong drug or dose; wrong quantity; damaged packaging; inadequate refrigeration; counterfeit product, etc.) and timely deliveries, both for routine and emergency deliveries. I also believe that the required physician call centers need to operate a minimum of 12 hours per day and that call management standards should tightly limit ring time, hold time, and dropped calls.

When it comes to Clinical Standards, I applaud CMS's decision to make the local carriers the arbiters of coverage and medical necessity decisions. In oncology, drugs can be extremely expensive, compendium-supported off-label usage is statutorily mandated, and off-label usage supported by peer-reviewed literature is also commonly reimbursed. As a result, CMS is right not to place decisions about coverage and medical necessity in the hands of vendors.

I am concerned, however, about the administrative burden on physician practices that will result from the CAP Election Agreement's requirement that physicians appeal all denied drug administration claims. The proposed rule provides no guidance on how many levels of appeal the physician must pursue, but the draft Election Agreement requires appeal through the reconsideration level. For clarity, we urge CMS to include this limitation in the final rule. The burden of appealing every denied drug administration claim is heightened by the pending changes in the claims appeal process that become effective on May 1, 2005. Given the magnitude of those changes, CMS should require the CAP vendor to request clinical literature from drug manufacturers needed to support appeals of drug administration denials.

I am also concerned that the proposed rule ignores the significant risk that physicians could face litigation over adverse drug events due to drugs provided by a CAP vendor. I strongly urge CMS to require CAP vendors to indemnify physicians for all costs, including reasonable attorney's fees, associated with the defense of all

such actions where the physician is ultimately exonerated. The indemnification may be prorated if the physician is found to be partly liable and there is a rational basis for apportioning costs between the CAP vendor and the physician.

With respect to Financial and Solvency Standards, I commend CMS's decision to assess CAP bidders using Federal Acquisition Regulation (FAR) criteria, adopt FAR business integrity and conflicts of interest standards, and review third-party information on the structure and effectiveness of CAP bidders' internal control systems. The proposed rule does not specify how CMS will ensure ongoing compliance with vendor performance requirements, however, so CMS should issue a detailed guidance document, require CAP vendors to report key performance statistics quarterly, and consider imposing contractually defined financial penalties for sub-par performance in addition to the imposition of False Claims Act liability that vendors face.

Contract Requirements

The World Health Organization estimates that 6% of all drugs distributed in the world are counterfeit and some observers believe it to be as high as 12%. Since most counterfeit drugs in the US enter the chain of commerce through the secondary market, I applaud Congress' decision to require CAP vendors to acquire all of their drugs directly from the manufacturer or from a wholesaler that buys direct.

Product integrity is about more than blocking the distribution of counterfeit goods, however. That is why I am concerned that the Proposed Rule's provisions could jeopardize product integrity and violate state licensing laws.
I suspect that CMS may not have thought through licensing and product integrity issues because it seems to have concluded that CAP vendors should be licensed as wholesalers but not as pharmacies. Indeed, many provisions in the Proposed Rule and the entire discussion of product integrity in the preamble focuses on wholesale distributors.
I am convinced that CAP vendors must be licensed as pharmacies, however. The statute does not expressly define the class of trade of a CAP vendor and 1847B(b)(4)(C) could suggest that Congress viewed CAP vendors as wholesalers. And yet, Social Security Act 1847B(b)(6) seems to take a different position, stating that nothing in Social Security Act 1847B 'shall be construed as waiving applicable State requirements relating to licensing of pharmacies.'
CAP vendors must be licensed as pharmacies because they will accept patient-specific written orders for prescription drugs from physicians, assign prescription numbers to those orders, interpret the orders, presumably making generic substitutions as appropriate and permissible under applicable State law, and then transfer dispensed drugs to the prescribing physician for administration to the patient. This patient-specific transfer amounts to 'dispensing' a drug under state pharmacy practice acts and because CAP vendors dispense, they are practicing pharmacy and must be licensed accordingly.
Since CAP vendors must operate as licensed pharmacies, some of the operational aspects of CAP seem unworkable or in need of retooling. For example, state pharmacies laws do not permit a pharmacist to assign different prescription numbers to successive fills of a single prescription. Rather, prescription refills are always dispensed under the prescription number assigned to the original written order. A new prescription number is assigned only when a new written order is received. These practices are inconsistent with the prescription numbering system described in the preamble to the Proposed Rule.

Another critical problem is posed by CMS's proposal for dealing with CAP drugs that cannot be administered to the beneficiary for whom they were prescribed. Most state pharmacy laws prohibit the restocking of unused drugs after they have been dispensed. By establishing a process for the restocking and use of previously-dispensed drugs, however, the proposed rule appears to put the physician in the position of aiding and abetting the violation of these state pharmacy laws. In fact, none of the laws of which I am aware allow dispensed product to be redirected to another patient without going back to the dispensing pharmacy first.

Redirecting unused drugs dispensed by a CAP vendor from the intended recipient to another patient could expose physician practices to tort liability. Physicians participating in CAP will therefore need indemnification from CAP vendors when reuse decisions about drugs belonging to the vendor, not the physician, are made based on discussions with the CAP pharmacist. CMS should build requirements for appropriate indemnities into the final rule.

Overview of the CAP

In its implementation of the Medicare Modernization Act of 2003 (MMA), the Centers for Medicare and Medicaid Services (CMS) has sought to more adequately cover the labor, supply, pharmacy, and other costs incurred in the administration of cancer-fighting drugs. Among the steps taken is the adoption of G codes to cover drug administration services and the creation of a demonstration project for 2005 that provided additional reimbursement.

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And yet, it is possible that neither CMS nor Congress has recognized that the viability of these two choices turns on the adequacy of reimbursement for drug administration services. Unless changes are made, many oncologists will face a loss under the buy-and-bill model, a loss that will be even greater should they opt to participate in CAP. This is because the only reimbursement they will receive under CAP is payment for drug administration services which will fall well below the cost of providing drug administration services.

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to Medicare beneficiaries altogether. Sadly, both approaches threaten the community cancer care services on which millions of Americans now depend.

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Bidding Entity Qualifications

CMS is justifiably concerned about the need to ensure that CAP vendors are qualified to provide the services called for under Social Security Act 1847B. I disagree, however, with two of the approaches that CMS has proposed for qualifying potential candidates.

CAP vendors must be licensed as a pharmacy in each state in their assigned service area. Although they may need to be licensed as a wholesaler as well, that credential alone is not sufficient because wholesalers are not permitted to ship patient-specific drug orders dispensed pursuant to a prescription. By focusing so extensively on distribution experience and the wholesaler credential, CMS is emphasizing the commodity aspect of the services that CAP vendors must provide, not the high-value aspects of those services.

Instead, CMS should focus on the dispensing aspects of a CAP vendor's duties and pharmacy credentials. Just as important, CMS should place great emphasis on vendors' competence in patient-centric drug management services, in billing, claims processing, coordination of benefits and collections, and in their responsiveness to local market needs. Licensed pharmacies are more likely to have experience dealing with patient and physician complaints and are more likely to have, and be used to operating under, a code of conduct and a robust compliance program like that envisioned under 42 CFR 414.914(c). It is these credentials that seem more relevant than CMS's current focus on distribution capabilities.

I also disagree with the proposal to require all acceptable applicants to have 3 years of experience in 'the business of furnishing Part B injectable drugs.' Years of experience as a distributor are a poor proxy for the skill sets and capacity measures that will characterize efficient and effective CAP vendors. Moreover, the 3-year requirement will restrict competition and prevent new and higher quality entities from entering the market. A better approach would be to require that a bidder hold current pharmacy and wholesaler licenses in each state in the service area for which it is bidding and be enrolled as a Medicare supplier. CMS should then evaluate each applicant's financial performance and solvency against pre-established criteria to identify organizations that are sufficiently capitalized to take on the challenge.

Similarly, CMS should collect information on personnel statistics, warehouse and dispensing capacities, distribution center locations, inventory sourcing relationships and the like and compare that information to pre-established criteria designed to ensure that the applicant has the wherewithal to handle the dispensing load CAP vendors can expected to face. It will be particularly important for vendors to have a broad geographic presence, either directly or through subcontract arrangements, with a wide network of pharmacies. Otherwise the vendor will be unable to make routine and emergency deliveries in time frames that meet patient needs.

CMS also should gather data about each applicant's experience in critical functions such as pharmacy services management, billing and collection, and compliance to evaluate the applicant's ability to provide the level of service and quality necessary to support physicians who furnish Part B drugs in their offices and the Medicare beneficiaries who depend on them for care. As part of this process, CMS should consider checking references to assess how satisfied customers of a size commensurate with that of most oncology practices have been with past service.

In each of these areas, the bidder's qualifications can be assessed not merely on the basis of their experience in the commodity service of distribution but in crucial service functions that will determine the difference between vendors who can safely and reliably serve CAP physicians needs, and those that cannot.

Claims Processing Overview

I am concerned that the proposed rule's delivery standards could pose a significant risk of increased financial and clinical costs to cancer patients. Today, cancer care practices routinely maintain a drug inventory to meet their patients' treatment needs. This has enabled practices to accommodate changes in patients' treatment plans without requiring the patient to return for therapy on another day. Under CAP, however, this level of service could be difficult if not impossible to maintain.

If chemotherapy sessions must be rescheduled to wait for the delivery of the drug(s) that patients need, they will face additional coinsurance obligations for the repeat physician services. In addition, patients will face other financial burdens in the form of higher transportation costs and additional missed time from work. This situation may also mean missed work time and reduced productivity for family members and other caregivers who must bring beneficiaries to the rescheduled treatment sessions.

I recognize that Social Security Act 1847B(b)(5) and the proposed rule permit physicians to receive replacement product from their CAP vendors for drugs taken from the physician's inventory. Even if CAP physicians had a sufficient inventory to draw from, this option appears too narrowly tailored to save most patients from having to undertake a return trip and bear the cost of an additional coinsurance payment. Specifically, the use of the replacement program is limited to situations where the physician builds a record to demonstrate all of the following to the local carrier: (1) the drugs were required immediately, (2) the physician could not have anticipated the patient's need for the drugs, (3) the CAP vendor could not deliver the drugs in a timely manner, and (4) the drugs were administered in an emergency situation.

There are a few glaring problems with the inventory replacement option. First, neither the statute nor the proposed rule defines 'emergency.' Moreover, neither the proposed rule nor the preamble discussion explains what a physician would have to show to justify immediate need or how the local carrier will assess whether the physician could have anticipated the patient's drug needs sufficiently far in advance to permit delivery via the CAP vendor. Aside from the risk that the claim for replacement drug will be denied by the local carrier, the administrative burden of building this record may discourage many physicians from using the inventory replacement option. The inventory replacement option also raises the question about whether commercial insurers are being asked to subsidize a portion of the drug

costs for Medicare beneficiaries in CAP, since Medicare would not be paying a physician for the ordering, financing, inventorying and handling costs associated with drugs borrowed from the practice's inventory.

I am even more concerned about what this option could mean for patients, since it is not at all clear that oncology practices will be able to maintain full inventories after the implementation of CAP. Depending on their patient bases, the range of drugs that some practices would need for Medicare beneficiaries may not be the same as the drug inventory that the practice would stock for commercial patients. Moreover, if CAP encourages the proliferation of mandatory vendor imposition (MVI) programs among commercial carriers, it is likely that some practices may stop maintaining drug inventories altogether.

In sum, patients may be forced to pay both a financial and clinical price for treatment disruptions due to CAP, potentially exposing them to medical complications and increased emergency hospitalizations in addition to repeat visits and higher cost-sharing obligations.

Dispute Resolution

According to the preamble to the Proposed Rule, CMS believes that CAP will not significantly increase the administrative burden on physicians. As a result, CMS has concluded that the payment for clerical and inventory management services that is bundled into the drug administration codes should be adequate to cover the practice expenses which physicians will occur under CAP. This is unrealistic for a number of reasons, including the following:
First, CAP practices will have to implement and operate a second, separate ordering process for CAP drugs to transmit patient-specific drug orders that include demographic and clinical information. The ordering system under the buy-and-bill model is much simpler because aggregate orders based on practice usage are placed with wholesalers. Buy-and-bill ordering does not involve the review of individual patient charts nor does it require input of substantial amounts of data for each vial of drug requested from the wholesaler. Second, CAP will increase the demands on oncology practices for pharmacy management services. Changes in individual treatment plans will have to be closely monitored so that new prescriptions can be sent to the vendor in timely fashion. The job of ensuring that drugs are given to the right patient and that patient-specific drug supplies provided in multi-dose vials have not expired or passed stability deadlines before the entire vial is used will be more complicated because the time that any particular multi-dose vial must be maintained and monitored will increase. The increases in complexity of required pharmacy management services will also increase the risk of medication errors.
A study of oncology pharmacy costs by the University of Utah on behalf of the Global Access Project suggests that the average cost of these services per dose of chemotherapy preparation is already $36.03. Since the current level of pharmacy services costs is not captured in the practice expense component of payments for drug administration services, the new costs imposed by CAP will be both additive and uncompensated. Third, CAP will likely increase hazardous waste disposal costs substantially due to complications regarding the redirection, in the physician's office, of unused drug dispensed for one patient to another patient. Waste handling costs will also be higher under CAP due to the increased likelihood that a drug designated for a particular patient will pass its expiration or stability deadline before all of the vial can be finished. As a result, total waste quantities could quickly exceed levels allowable for routine disposal, thereby adding even greater costs. Fourth, CAP physicians will face much higher claims administration costs. CAP requires Medicare claims for drug administration services to be filed within 14 days of the drug administration service. This represents an increased burden since the Proposed Rule acknowledges that only about 75% of claims currently are filed within this timeframe and since claims processing software will need to be upgraded. Further, CAP physicians will be unable to make a cost-benefit decision about the value of appealing a claim denial for drug administration services. Instead, physicians could be forced to appeal all denials in a process that requires all the evidence needed to support the appeal to be collected and submitted. Given the management, inventory control, drug preparation, paperwork, integrity assurance, and other necessary new or enhanced functions that will face physicians selecting CAP, CMS should establish a new HCPCS code for pharmacy management services to compensate physicians. To address the hazardous waste disposal problem, CMS should also require each CAP vendor to subcontract with properly licensed and permitted hazardous waste haulers and disposers to pick up from physicians discarded drugs dispensed by the vendor and to destroy those drugs in accordance with applicable federal, state & local laws.

Submitter : Mrs. Kim Prather **Date:** 04/11/2005

Organization : Jackson Oncology Associates

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

I would like to address what appears to be lack of understanding about the time/paperwork for physician practices under the CAP Vendor proposal. Maintaining separate inventory (added time/resources), communication to/from CAP vendor (since it would be necessary to verify/maintain patient inforomation in order to bill for our services, as well as provide it for the vendor), purchase of drug 'by patient' (creates additional complication when there is possible redistribution if/when that patient doesn't receive the treatment---and this happens commonly---formerly drugs were anticipated and bulk-ordered regardless of a particular patient-larger quantity could be purchased & distributed as needed), documentation of RX # to identify drug being administered on the claim (cost incurred for system vendor to accomodate or additional manual entry of the information, if not), retrieval of CAP vendor billing info when physician staff remains responsible for handling vendor reviews/appeals (we must know if review is due to vendor error, carrier error, etc. before appeal can be initiated...we feel the CAP vendor should be required to handle reviews as the vendor can obtain access to physician record, if needed and knows what was billed and why). Additionally, the physician collection process does not decrease...we must still bill and collect for our services (statements, etc. costs the same regardless of the amount owed), counseling patients on their potential out-of-pocket expense, which will then include explanation of co-insurance to be billed by the vendor (in order to prepare financial resources for those patients with special needs) and maintain staff to retrieve/handle reviews, etc. Medical team responsibility would likely increase due to additional inventory and ordering requirements. I fail to see where time, paperwork and/or physician responsibility and liability is decreased at all. It is only right and reasonable to provide a billable fee to offset these asserted costs to the physician. Thank you.

Submitter : **Ms. Debra Seyfried** **Date: 04/11/2005**

Organization : **Charleston Cancer Center**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Competitive Acquisition of Outpaitent Drugs and Biologicals is a flawed endeavor. No one can address the liability issue that it forces on physicians. Physicians and clinic are already being hit by incredulous premiums and this opens a pandora's box.

It doesn't cover the waste and control of the drug wastage and/or payment for disposal.

It doesn't cover changes in chemotherapy that occur routinely.

Most importantly it doesn't address the burden placed on our senior population for the copayment, that in our office at least, is worked out with the patient in a civilized manner. Has anyone thought through what will happen to these patients when someone who doesn't see or know them, doesn't care about their health only the $$ collections, demands money from these elderly patients in compromised health? These people were raised in a post depression era where frugality was encouraged. Many of our poor cannot afford to pay the 20% copayment. I can guarantee you the Middleman will not care. You are forcing these patients to choose life and death and by cutting the reimbursements so severely as you have and looking a programs like these it causes the average oncologist to address life and death of thier practices and livlihood.

I encourage you not to proceed with these programs until these issues have been addressed. This is not a band-aid situation.

Submitter : **Mr. Peter Muhlbach** **Date: 04/11/2005**

Organization : **North Shore Oncology**

Category : **Other Health Care Professional**

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

Instead of diving into a national CAP involving all Part B drugs used in ?incident to? services, CMS should begin with a regional or national test involving a limited set of drugs that are typically administered by a physician specialty that uses drugs less intensely than oncology. This would allow CMS to refine its application and vendor selection procedures and its quality and service requirements, correct glitches in CAP upgrades to its claims processing systems, work out handling issues stemming from state regulations, assess and adjust for changes in practice expenses attributable to CAP, and complete the work needed to better match the reimbursement rates for drug administration services to actual costs for the various specialties before CAP is implemented more universally.

Competitive Acquisitions Areas

A key issue relating to Competitive Acquisition Areas is the requirement that CAP vendors have arrangements in place sufficient to permit shipment ?at least 5 days each week for competitively biddable drugs and biologicals . . . and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract.? (See also 42 CFR 141.914(f)(2)). We appreciate CMS?s request for comments both on ?how to define timely delivery for routine and emergency drug shipments? and on the ?feasibility of providing same day deliveries for orders received for emergency situations? (70 Fed. Reg. 10745,10760 (March 4, 2005)).

I believe that the proposed timelines for routine and emergency delivery are inadequate and that vendors must be required to make routine deliveries anywhere in their service area within 24-hours of a practice?s submission of a new prescription 7 days a week. I base this recommendation on three principle considerations. First, it is not unusual for oncology practices to operate 6 and 7 days a week to meet their patients? needs. Second, it is estimated that approximately one-third of treatment plans must be modified on the day of treatment due to changes in a patient?s health status. Third, the unavailability of drugs needed on the day of treatment would pose a significant burden on patients who would have to return another day for treatment. This burden can be particularly severe in rural areas were patients may have to travel long distances to receive cancer care.

CMS has the authority to require that CAP vendors be able to delivery drugs within 24 hours 7 days a week under the statutory language in Social Security Act ?1847B(b)(2)(A)(i)(II). That provision imposes two standards on CAP vendors: the ability to make timely deliveries and the ability to ship at least 5 days each week. I believe that CMS should use its authority to define ?timely delivery? as a 24-hour turn around and 7-day-a-week delivery services. I fear that anything less could jeopardize the ability of cancer care specialists to meet their patients? clinical needs.

I believe CMS should not rely on an expectation that oncologists who choose CAP will continue to maintain an adequate inventory of drugs that can be used to treat Medicare patients in emergencies under the inventory replacement provisions of the CAP rule. CAP is expected to spur growth in commercial payers? mandatory vendor imposition (MVI) programs. As a result, some physicians who elect CAP and continue offering in-office drug administration services may cease to maintain any on-site drug inventories. Even those practices that maintain inventories may limit them for a variety of reasons, including differences in the clinical needs of their Medicare and non-Medicare patient bases.

Finally, I note that neither the changes to 42 CFR 414.902 set forth in the proposed rule nor the text of the existing regulation define the term ?emergency.? It is essential for the definition of emergency to be clearly set forth in the final rule and not left to the discretion of each CAP vendor or to the discretion of local carriers tasked with adjudicating practices? claims for drug administration services. Moreover, the definition should turn on the treating physician?s clinical judgment that patient health would suffer from delay in treatment, not on the CAP vendor?s or the local carrier?s remote assessment of the situation.

In closing, I respectfully urge CMS to implement the ?timely delivery? requirement established by MMA as requiring CAP vendors to be able to deliver ordered drugs within 24 hours, 7 days a week.

Statutory Requirements Concerning Claims Processing

I am concerned that the proposed rule?s delivery standards could pose a significant risk of increased financial and clinical costs to cancer patients. Today, cancer care practices routinely maintain a drug inventory to meet their patients? treatment needs. This has enabled practices to accommodate changes in patients? treatment plans without requiring the patient to return for therapy on another day. Under CAP, however, this level of service could be difficult if not impossible to maintain.

If chemotherapy sessions must be rescheduled to wait for the delivery of the drug(s) that patients need, they will face additional coinsurance obligations for the repeat physician services. In addition, patients will face other financial burdens in the form of higher transportation costs and additional missed time from work. This situation may also mean missed work time and reduced productivity for family members and other caregivers who must bring beneficiaries to the rescheduled treatment sessions.

I recognize that Social Security Act 1847B(b)(5) and the proposed rule permit physicians to receive replacement product from their CAP vendors for drugs taken from the physician?s inventory. Even if CAP physicians had a sufficient inventory to draw from, this option appears too narrowly tailored to save most patients from having to undertake a return trip and bear the cost of an additional coinsurance payment. Specifically, the use of the replacement program is limited to situations where the physician builds a record to demonstrate all of the following to the local carrier: (1) the drugs were required immediately, (2) the physician could not have anticipated the patient?s need for the drugs, (3) the CAP vendor could not deliver the drugs in a timely manner, and (4) the drugs were administered in an emergency situation.

There are a few glaring problems with the inventory replacement option. First, neither the statute nor the proposed rule defines ?emergency.? Moreover, neither the proposed rule nor the preamble discussion explains what a physician would have to show to justify immediate need or how the local carrier will assess whether the physician could have anticipated the patient?s drug needs sufficiently far in advance to permit delivery via the CAP vendor. Aside from the risk that the claim for

replacement drug will be denied by the local carrier, the administrative burden of building this record may discourage many physicians from using the inventory replacement option. The inventory replacement option also raises the question about whether commercial insurers are being asked to subsidize a portion of the drug costs for Medicare beneficiaries in CAP, since Medicare would not be paying a physician for the ordering, financing, inventorying and handling costs associated with drugs borrowed from the practice?s inventory.

I are even more concerned about what this option could mean for patients, since it is not at all clear that oncology practices will be able to maintain full inventories after the implementation of CAP. Depending on their patient bases, the range of drugs that some practices would need for Medicare beneficiaries may not be the same as the drug inventory that the practice would stock for commercial patients. Moreover, if CAP encourages the proliferation of mandatory vendor imposition (MVI) programs among commercial carriers, it is likely that some practices may stop maintaining drug inventories altogether.

In sum, patients may be forced to pay both a financial and clinical price for treatment disruptions due to CAP, potentially exposing them to medical complications and increased emergency hospitalizations in addition to repeat visits and higher cost-sharing obligations.

Overview of the CAP

With the implementation of the Medicare Modernization Act of 2003 (MMA), CMS has sought to more adequately cover the labor, suply, pharmacy, and other overhead costs incurred in the administration of cancer-fighting drugs. With the demonstation project and the drug administration transitional factor coming to an end on January 1, 2006, community cancer care physicians are being put "between a rock and a hard place". The viability of the two choices, i.e. CAP or ASP,turns on the adequacy of reimbursement for drug administration services. Unless changes are made for 2006, many community cancer care physicians will be forced to discontinue offering chemotherapy services to Medicare beneficiaries and these Medicare cancer patients will recieve their chemotherapy at the hospital. Patient access to community cancer care must be preserved since it is the source of convenient, cost effective care for more than 80% of American cancer patients. Therefore, I urge CMS to extent the quality demonstration project and/or increase the drug administration transitional factor until such time as the issues with CAP and ASP are resolved.

Submitter : Mr. Dewayne Long **Date:** 04/12/2005

Organization : NAMI Southwest Missouri

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

"See attachment"

CMS-1325-P-87-Attach-1.DOC

April 11, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
PO BOX 8010
Baltimore, MD 21244-8010

Dear CMMS:

I am writing in support of the Competitive Acquisition Program (CAP) to provide consumer access to mental health therapies.

Currently, consumers are affected through a system that does not support innovation and a process that is time consuming and provides inadequate coverage. CAP provides some solutions to the problems by adopting practices that support consumer access and services.

NAMI Southwest Missouri is supportive because of the ease by which Competitive Acquisition Program can assist with out necessary delays in treatment.. It first improves consumer access to care which is vitally important to the quality of life for the individuals. Secondly, it allows injectables to be handled as a pill. Third, it eliminates issues exist regarding eligibility coverage and process. CAP includes all therapies and ensures pharmacy provider vendors maintain product availability.

The neediest individuals affected with mental illness must have quick and available treatment and mediations that enhance their abilities to cope with illness and have stability in their lives. Again, we support this effort to improve the system so that our friends and family members with mental illness can be treated efficiency and without delays

Dewayne Long
Executive Director

Submitter : **Mrs. Jennifer Alfredson** **Date: 04/12/2005**

Organization : **Health Care for the Homeless**

Category : **Social Worker**

Issue Areas/Comments

GENERAL

GENERAL

I would like to state my opinion that psychiatric medications be included in the Medicare Part B competitive acquisition of outpatient drugs and biologicals. In my job as a Social Worker, I encounter people with Medicare as their primary insurance on a daily basis. Many of these people cannot afford the prescriptions that they need to live a normal life. Many of these people suffer with their mental health on a daily basis.I have observed that when people are not doing well psychiatrically, they also tend to have increased physical illnesses. Therefore, by ignoring the needs of the psychiatric population, it will not only hurt these people daily, it will drive up the cost of other physical medications, hospitalizations, and procedures.

Submitter : Mr. Matthew Mc Garvey **Date: 04/12/2005**

Organization : The Center for Rheumatology, LLP

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1325-P-89-Attach-1.DOC

April 12, 2005

Mr. Mark B. McClellan
Center for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS 1325-P
Competitive Acquisition of Drugs and Biologicals Under Part B

Dear Mr. McClellan:

On behalf of the physicians and patients of The Center for Rheumatology, LLP, I am writing to officially comment on the proposed rule regarding Competitive Acquisition of Drugs and Biologicals Under Part B. A Competitive Acquisition Program (CAP) is contrary to the concept of administrative simplification.

Our practice of 8 physicians provided approximately 8,400 services to Medicare beneficiaries during 2004, representing 31 percent of our entire practice. Our group collectively forms the largest single specialty Rheumatology practice in upstate of New York, serving patients that encompass a 200-mile radius. Rheumatologists administer care to not only patients with Rheumatoid Arthritis, but those with Osteoarthritis, Osteoporosis, Lupus, Fibromyalgia, Gout, Psoriatic Arthritis, Sjogrens Syndrome, Lyme Disease, Scleroderma and many other connective tissue and musculoskeletal diseases.

I understand that providers who wish to engage in a CAP will take on the added administrative responsibilities in maintaining an individual patient inventory of each Part B drug that is shipped to the practice from the CAP vendor or pharmacy. It is our understanding that this will occur without any additional reimbursement to the provider. By adopting a CAP program, providers are essentially being put in the "inventory business" by maintaining a personal inventory of drugs for each individual patient. It would be the responsibility of the provider to include the order information such as frequency and instructions, the anticipated date of administration, information about the patient's secondary insurance, date of birth, allergies, height,

weight, etc. Drugs for each patient would be shipped to the practice on a schedule and it will be the responsibility of the provider to maintain the inventory. CAP drugs would need to be stored separately from other drugs. If drug supplied by a vendor is not administered on the "expected date of administration," the physician would notify the vendor in each instance and they would "reach an agreement" on how to handle that drug. The system also seems to lack a solution for situations where the physician wishes to escalate the dose of the medicine at the time of service. Will providers be compensated fairly and promptly for taking drug out of their stock for a patient in need?

This would require the dedication of staff time, storage space, refrigeration, and the development of an inventory system that would undoubtedly include constant communication with the vendor. I feel that this process is SIGNIFICANTLY more work than what is being done in practices around the country, including this one. It is unreasonable to expect that in the age of rising costs to run a physician practice, this type of resources can be dedicated to this process without any additional reimbursement.

After the drug is administered, the physician will need to file a claim that includes the Rx drug number and the J-code on a CMS-1500 claim form within 14 days. Based on this proposal, it will be the responsibility of the provider to work with their practice management software vendor to make certain that the Rx number for the Medicare drug is on the CMS-1500 claim form. This appears to be a new responsibility of the provider that will again be uncompensated. How can CMS justify the resources involved in having the providers working with their practice management software vendor to "re-write" an already compliant format in order to provide this information?

Patients have become accustomed to receiving bills for any balances from the provider and the EOMB from Medicare. Under a CAP, the provider will be responsible for having the J-code and Rx number on their claim form, yet CMS will make payment to the vendor. From there the vendor will be responsible for collecting the co-insurance from the patient. Under such a fractured billing and reporting system, the provider is out of the "cost loop" and will be in a difficult position to provide financial counseling and make payment arrangements with the patient. What will happen if the vendor is unable to obtain payment for the co-insurance from the patient? Will he or she be "cut-off" or sent to collection? This will remove the physician from the decision making process.

How will a CAP handle the issue of medications that come in multi dose vials? If each vial of medication will arrive to the provider individually assigned to a patient, how will this system work for medicines with multiple doses in the same vial? This appears to be an area that is ripe for confusion, and one where confusion can easily arrive as the provider attempts to put the proper Rx number on the claim form for each patient.

I feel that the entire concept of Part B drug reimbursement would be incomplete without further comment on the Average Selling Price based reimbursement system. The calculation of an Average Selling Price reimbursement system for Medicare drugs is in need of re-

examination. As part of the ASP system, manufactures are required to disclose to CMS any "discounts" including rebates to managed care. CMS, in turn, uses these discounts in the ASP calculation. This inclusion is artificially lowering the ASP and therefore artificially lowering the reimbursement to providers on Medicare drugs. The fact that a correlation between managed care discounts and Medicare Drug reimbursement is unfair to providers who provide drugs to Medicare beneficiaries in their office. I do not understand the correlation. These discounts should be removed immediately and create a more accurate calculation.

It is significant to look at Part B drug reform in the context of any alternative settings to the physician office. If physicians are not fairly reimbursed for providing Medicare drugs in their office and reimbursements do not keep up with rising costs, access to the services for Medicare beneficiaries might become restricted. The physician's office is the patient preferred setting to provide infusible medicines. We have data to prove it. It is also the safest and, compared to the hospital outpatient setting, more cost-effective. CMS must be sensitive to the relationship between fair reimbursement and preserving access for patients.

Respectfully submitted,

MATTHEW P MCGARVEY

Matthew P. Mc Garvey, MBA
Practice Administrator

Submitter : Dr. J. Scott Nystrom **Date:** 04/12/2005

Organization : Great Lakes Cancer Management Specialists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

As a practicing Oncologist and admnstrator for a moderately large specialty group I have some serious doubts regarding the implementation of CAP.
1] When drug is shipped from an outside vendor and because of medical reasons it cannot be adminstered do we retrun the drug? or is it wasted? Does the phsycian group bear any financial responsibility for the non payment of drug?
2]Patients who do not have insurance for the 20% copay will the CAP vendor be required to ship and proide drug to a patient who may not be able to pay? Will these patients be denied care? Under current system individual cases are still cared for through social agencies, etc.,
3] When drug is shipped damaged and cannot be given to the patient and the treatment protocol is time sensitive how does the oncolgosit provide drug in this cirmcumstance? Or does the patient jeopardize his treatment plan by waiting until new drug is shipped?
4] Our practice groups expected to absorb the extra costs involved in tracking separately inventory and storage for these patients receiving drugs from a CAP vendor who is an entirely different vendor from those patients i private pay?

Submitter : **Dr. William Berry** **Date: 04/12/2005**

Organization : **Cancer Centers of North Carolina**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

As a busy oncologist who takes care of patients, I find it very disheartening to have to solicit the government not to destroy our cancer delivery system that has deveoped over the last thirty years. I do not oppose a more rationale system of paying for injectable drugs than the one we have had, but along with revision of the payment for drugs, there must be a revision upward in paymeny for infusional services and for evaluation and management codes for cancer patients, or we will be unable to afford to treat patients in the outpatient seting. Nor will dismantling our outpatient infusion services and treating patients in the hospital be a cost effective or practical strategy. Please consider the complexity of the system required to deliver care to cancer patients in an outpatient setting-come visit our offices-we cannot let the system be destroyed .

Submitter : **Ms. Elizabeth Mills** **Date: 04/12/2005**

Organization : **Arlington County**

Category : **Comprehensive Outpatient Rehabilitation Facility**

Issue Areas/Comments

GENERAL

GENERAL

Please include the coverage of psychotropic medication in this bill. Thank you.

Submitter : Mrs. Jan Hall **Date: 04/12/2005**

Organization : Wasatch Mental Health

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1325-P-93-Attach-1.DOC

April 12, 2005

Center for Medicare and Medicaid Services
Salt Lake City, Utah

To Whom It May Concern:

I have been asked to write this letter outlining a few of the billing and reimbursement problems we are currently encountering at Wasatch Mental Health (WMH) regarding Risperdal Consta.

- Submission of the same claim several times due to lack of complete information from Medicare when first call is made by WMH to correct billing errors.
- Medication pre-purchased by WMH in good faith that all expenditure for medication will be recouped. However, client deductible is withheld from remit to WMH causing a considerable loss in revenue that now needs to be billed to a second, possibly unreliable payment source (client).
- Slow response from Medicare supervisors when returning call to WMH after being asked to provide further explanation as to why claim denied again when information on claim appeared to be in order.

Due to these billing problems, WMH has suspended putting additional clients on Risperdal Consta and may discontinue its use as an injection on current clients if billing problems cannot be resolved soon.

Thank you for you time and attention to these problems.

Sincerely,

Jan Hall
Billing Coordinator
Wasatch Mental Health

Submitter : **Dr. Peter Tortorice** **Date: 04/12/2005**

Organization : **US Oncology**

Category : **Pharmacist**

Issue Areas/Comments

1-15

Overview of the CAP

In its implementation of the Medicare Modernization Act of 2003 (MMA), the Centers for Medicare and Medicaid Services (CMS) has sought to more adequately cover the labor, supply, pharmacy, and other costs incurred in the administration of cancer-fighting drugs. Among the steps taken is the adoption of G codes to cover drug administration services and the creation of a demonstration project for 2005 that provided additional reimbursement.

As a result, 2005 Medicare reimbursement for cancer care services is considerably higher than pre-MMA rates. However, total reimbursement will drop dramatically on January 1, 2006, when the demonstration project is scheduled to end and the drug administration transitional factor will be zeroed out.

It has been calculated that the impact of these changes will translate into a $940 underpayment for drug administration services per Medicare beneficiary. Put another way, 2006 Medicare reimbursement for patient care services will cover only an estimated 50.09% of drug administration costs.

This problem is a key factor in the implementation of the Competitive Acquisition Program (CAP) in 2006. Under CAP, middlemen vendors will furnish drugs to physicians who choose to give up the traditional buy-and-bill model and select the CAP model instead. The vendors will be responsible for billing Medicare for the drugs, and the physicians will receive reimbursement only for drug administration services.

CMS expects CAP to appeal to those physicians ?who do not want to be in the drug procurement and drug coinsurance collection business? [70 Fed. Reg. 10750]. Indeed, statements made by CMS and CAP?s Congressional authors all reinforce the notion that CAP is intended to be an option that physicians may choose to adopt in place of the current buy-and-bill model. According to the MMA Conference Report produced by Congress, ?Conferees intend this choice to be completely voluntary on behalf of the physicians? [H. R. Conf. Rep. No. 108-391, 108th Cong., 1st Sess. 593 (2003)].

And yet, it is possible that neither CMS nor Congress has recognized that the viability of these two choices turns on the adequacy of reimbursement for drug administration services. Unless changes are made, many oncologists will face a loss under the buy-and-bill model, a loss that will be even greater should they opt to participate in CAP. This is because the only reimbursement they will receive under CAP is payment for drug administration services ? which will fall well below the cost of providing drug administration services.

In light of the reimbursement shortfall that looms on January 1, 2006, many cancer care specialists will face a very different choice than the one that Congress intended: continue to offer cancer care services to seniors (under buy-and-bill or CAP) and incur a significant net loss?or discontinue offering chemotherapy services to Medicare beneficiaries altogether. Sadly, both approaches threaten the community cancer care services on which millions of Americans now depend.

Congress has clearly stated its intent that patient access to community cancer care must be preserved because it is the source of convenient, cost-effective care for more than 4-out-of-5 American cancer patients. If CMS intends to abide by this intent, it must take additional steps to align Medicare reimbursement with the cost of drug administration services.

Because the level of needed fee schedule restructuring is significant, CMS may be unable to solve this pending crisis before the 2006 Physician Fee Schedule must be published. As a result, I urge CMS to extend the quality demonstration while it works to match drug administration cost and payments. Otherwise, both the CAP and the ASP models will be doomed to failure and many Medicare cancer patients likely will be forced back to hospitals for chemotherapy.

Submitter : Mrs. Barbara Davis **Date:** 04/12/2005

Organization : Western Tidewater Community Services Board

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

The Western Tidewater Community Services Board strongly urges CMS to include categories of psychiatric medications in its CAP project. This would be a great benefit to consumers with serious mental illness and their treating physician. Currently, the process is convoluted and costly. Allowing psychiatric medications, including long-acting injectables, to be part of CAP will streamline the acquisition process, reduce administrative and billing overhead, and allow those same resources to be focused on positive consumer outcomes, thus reducing episodes that require the most expensive care-hospitalization. Thank you.

Submitter : **Mr. Roland Gutierrez** **Date: 04/12/2005**

Organization : **Border Region MHMR**

Category : **Comprehensive Outpatient Rehabilitation Facility**

Issue Areas/Comments

GENERAL

GENERAL

Border Region MHMR Supports the following issues and would encourage the inclusion in the CAP Proposed Rule.

-Inclusion of Psychiatric Drugs.
-Inclusion of Psychiatric Drugs in Phase I.
-Inclusion of Mental Health Drug Category.
-Ensure Rule Prevents Discontinuation of Therapies by Vendors.

Mental Health issues have always been placed on the backburner in this country. CAP proposed rule changes must include the above issues. This will insure that our consumers receive quality care and are treated with the most effective drugs on the market. If these issues are not included it will cause us to limit services to individuals we currently serve. This could have a detrimental effect on other areas such as increased prison populations and increased homelessness.

Submitter : Ms. Rusty Smith **Date:** 04/12/2005

Organization : Spindletop MHMR Services

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

We support the CAP Program for dually eligible consumers to receive Risperdal Consta.

Submitter : **Dr. James Jacobson** **Date: 04/13/2005**

Organization : **Mercy Behavioral Health**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

My understanding is that CMS may favor starting CAP for oncology drugs only, not including psychiatric medications. Psychiatric medications must be included from the get go in order to improve access to psychiatric injectables, which are now difficult at access. The buy and bill system is an inherent barrier in the current system and it must be rectified with a proper implementation of the MMA.

Submitter : Dr. Richard Shapiro **Date:** 04/13/2005

Organization : Dr. Richard Shapiro

Category : Physician

Issue Areas/Comments

1-15

Competitive Acquisitions Areas

A key issue relating to Competitive Acquisition Areas is the requirement that CAP vendors have arrangements in place sufficient to permit shipment ?at least 5 days each week for competitively biddable drugs and biologicals . . . and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract.? (See also 42 CFR 141.914(f)(2)). We appreciate CMS?s request for comments both on ?how to define timely delivery for routine and emergency drug shipments? and on the ?feasibility of providing same day deliveries for orders received for emergency situations? (70 Fed. Reg. 10745,10760 (March 4, 2005)).

I believe that the proposed timelines for routine and emergency delivery are inadequate and that vendors must be required to make routine deliveries anywhere in their service area within 24-hours of a practice?s submission of a new prescription 7 days a week. I base this recommendation on three principle considerations. First, it is not unusual for oncology practices to operate 6 and 7 days a week to meet their patients? needs. Second, it is estimated that approximately one-third of treatment plans must be modified on the day of treatment due to changes in a patient?s health status. Third, the unavailability of drugs needed on the day of treatment would pose a significant burden on patients who would have to return another day for treatment. This burden can be particularly severe in rural areas were patients may have to travel long distances to receive cancer care.

CMS has the authority to require that CAP vendors be able to delivery drugs within 24 hours 7 days a week under the statutory language in Social Security Act ?1847B(b)(2)(A)(i)(II). That provision imposes two standards on CAP vendors: the ability to make timely deliveries and the ability to ship at least 5 days each week. I believe that CMS should use its authority to define ?timely delivery? as a 24-hour turn around and 7-day-a-week delivery services. I fear that anything less could jeopardize the ability of cancer care specialists to meet their patients? clinical needs.

I believe CMS should not rely on an expectation that oncologists who choose CAP will continue to maintain an adequate inventory of drugs that can be used to treat Medicare patients in emergencies under the inventory replacement provisions of the CAP rule. CAP is expected to spur growth in commercial payers? mandatory vendor imposition (MVI) programs. As a result, some physicians who elect CAP and continue offering in-office drug administration services may cease to maintain any on-site drug inventories. Even those practices that maintain inventories may limit them for a variety of reasons, including differences in the clinical needs of their Medicare and non-Medicare patient bases.

Finally, I note that neither the changes to 42 CFR 414.902 set forth in the proposed rule nor the text of the existing regulation define the term ?emergency.? It is essential for the definition of emergency to be clearly set forth in the final rule and not left to the discretion of each CAP vendor or to the discretion of local carriers tasked with adjudicating practices? claims for drug administration services. Moreover, the definition should turn on the treating physician?s clinical judgment that patient health would suffer from delay in treatment, not on the CAP vendor?s or the local carrier?s remote assessment of the situation.

In closing, I respectfully urge CMS to implement the ?timely delivery? requirement established by MMA as requiring CAP vendors to be able to deliver ordered drugs within 24 hours, 7 days a week.

Overview of the CAP

total reimbursement will drop dramatically on January 1, 2006, when the demonstration project is scheduled to end and the drug administration transitional factor will be zeroed out.

It has been calculated that the impact of these changes will translate into an underpayment for drug administration services per Medicare beneficiary. Put another way, 2006 Medicare reimbursement for patient care services will cover only an estimated 50.09% of drug administration costs. This will prevent services from being performed or done so in a suboptimal fashion.

This problem is a key factor in the implementation of the Competitive Acquisition Program (CAP) in 2006. Under CAP, middlemen vendors will furnish drugs to physicians who choose to give up the traditional buy-and-bill model and select the CAP model instead. The vendors will be responsible for billing Medicare for the drugs, and the physicians will receive reimbursement only for drug administration services.

CMS expects CAP to appeal to those physicians ?who do not want to be in the drug procurement and drug coinsurance collection business? [70 Fed. Reg. 10750]. Indeed, statements made by CMS and CAP?s Congressional authors all reinforce the notion that CAP is intended to be an option that physicians may choose to adopt in place of the current buy-and-bill model. According to the MMA Conference Report produced by Congress, ?Conferees intend this choice to be completely voluntary on behalf of the physicians? [H. R. Conf. Rep. No. 108-391, 108th Cong., 1st Sess. 593 (2003)].

And yet, it is possible that neither CMS nor Congress has recognized that the viability of these two choices turns on the adequacy of reimbursement for drug administration services. Unless changes are made, many oncologists will face a loss under the buy-and-bill model, a loss that will be even greater should they opt to participate in CAP. This is because the only reimbursement they will receive under CAP is payment for drug administration services ? which will fall well below the cost of providing drug administration services.

In light of the reimbursement shortfall that looms on January 1, 2006, many cancer care specialists will face a very different choice than the one that Congress intended: continue to offer cancer care services to seniors (under buy-and-bill or CAP) and incur a significant net loss?or discontinue offering chemotherapy services to Medicare beneficiaries altogether. Sadly, both approaches threaten the community cancer care services on which millions of Americans now depend.

Congress has clearly stated its intent that patient access to community cancer care must be preserved because it is the source of convenient, cost-effective care for more than 4-out-of-5 American cancer patients. If CMS intends to abide by this intent, it must take additional steps to align Medicare reimbursement with the cost of drug administration services.

Because the level of needed fee schedule restructuring is significant, CMS may be unable to solve this pending crisis before the 2006 Physician Fee Schedule must be published. As a result, I urge CMS to extend the quality demonstration while it works to match drug administration cost and payments. Otherwise, both the CAP and the ASP models will be doomed to failure and many Medicare cancer patients likely will be forced back to hospitals for chemotherapy.

Submitter : Dr. Vikas Malhotra

Organization : FLORIDA CANCER INSTITUTE

Category : Physician

Date: 04/13/2005

Issue Areas/Comments

GENERAL

GENERAL

I HAVE SERIOUS CONCERNS ABOUT MAINTAINING THE SAFETY OF THE MEDICATION PIPELINE IF THE COMPETITIVE ACQUISITION IS PUT INTO PLACE AS I WILL TAKE THE LIABILITY FOR THE SIDE EFFECTS BUT HAVE NO QUALITY CONTROL OVER HOW DRUGS ARE ACQUIRED OR MIXED. PLEASE RE-CONSIDER THIS PROPOSAL.

Submitter : Mrs. deborah lucente **Date:** 04/13/2005

Organization : primary oncology network

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I beleive that the proposal will be detrimental to the cancer patients who receive their treatments in physician offices. There are so many factors to be considered when providing patient care and treatments in the office setting. I don"t see how we will be able to obtain chemo medications in a timely; cost efficent manner if we must rely on a vendor to provide us with the medications. The patients must have lab work, an exam by a physician, an evaluation by the nursing staff in order to determine treatment decisions. It will be very expensive and wastful if drugs are sent and not used. Also, if drugs are premixed and damaged in shipment this would be another problem. As a nurse who has provided cancer care over 10 years to many hundreds of patients I can"t see that this will save the system money and resourses in the long run.

Submitter : Ms. Amy King **Date:** 04/13/2005

Organization : Nebraska Hematology-Oncology, P.C.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1325-P-102-Attach-1.DOC

On March 4, 2005 the Centers for Medicare and Medicaid Services (CMS) published proposed regulations establishing the Competitive Acquisition Program (CAP) for Medicare Part B drugs.

As a practice administrator for a community oncology practice I am very concerned about the outcome of this proposal and very disappointed that this proposal has been made without input from the people who take care of cancer patients in the community oncology setting on a daily basis. The CAP program needs to be tested on a smaller scale prior to implementation so there is an analysis of the true impact this system will have on patient care.

The CAP program will not create any additional cost savings, but will only further burden the system with inefficiency and additional cost. Patients will be inconvenienced and will need to return to the office for treatment as their drugs will need to be ordered prior to treatment. The CAP system is intended to take the drug purchasing business out of the hands of physicians and put it in the hands of specialty pharmacy, yet the costs to maintain this type of system will not decrease, but will create additional administrative and costly burdens to physician practices. The CAP program will change practices from one inventory systems, to multiple inventories, and most likely individual patient inventories. This system will create an increase potential for drug waste.

I have concerns that the CAP system will interfere with our patient/physician relationship and will add to the psychological issues cancer patients face. We feel that everyone should be able to receive the treatment they need and for this reason we work very hard with patients who are unable to pay or who need to make payment arrangements. I highly doubt that commercial vendors will be willing to accept payment delays from patients, forcing many to forgo treatment because of their inability to pay.

Please consider the issues discussed below and be certain CMS has a full understanding of the potential impact BEFORE jeopardizing the care millions of cancer patients rely on.

Issue Identifier: Overview of CAP

In its implementation of the Medicare Modernization Act of 2003 (MMA), the Centers for Medicare and Medicaid Services (CMS) has sought to more adequately cover the labor, supply, pharmacy, and other costs incurred in the administration of cancer-fighting drugs. Among the steps taken is the adoption of G codes to cover drug administration services and the creation of a demonstration project for 2005 that provided additional reimbursement. However, total reimbursement will drop dramatically on January 1, 2006, when the demonstration project is scheduled to end and the drug administration transitional factor will be zeroed out.

It has been calculated that the impact of these changes will translate into a $940 underpayment for drug administration services per Medicare beneficiary. Put another way, 2006 Medicare reimbursement for patient care services will cover only an estimated 50.09% of drug administration costs.

This problem is a key factor in the implementation of the Competitive Acquisition Program (CAP) in 2006. Under CAP, middlemen vendors will furnish drugs to physicians who choose to give up the traditional buy-and-bill model and select the CAP model instead. The vendors will be responsible for billing Medicare for the drugs, and the physicians will receive reimbursement only for drug administration services.

CMS expects CAP to appeal to those physicians "who do not want to be in the drug procurement and drug coinsurance collection business" [70 *Fed. Reg.* 10750]. Indeed, statements made by CMS and CAP's Congressional authors all reinforce the notion that CAP is intended to be an option that physicians may choose to adopt in place of the current buy-and-bill model. According to the MMA Conference Report produced by Congress, "Conferees

intend this choice to be completely voluntary on behalf of the physicians" [H. R. Conf. Rep. No. 108-391, 108th Cong., 1st Sess. 593 (2003)].

And yet, it is possible that neither CMS nor Congress has recognized that the viability of these two choices turns on the adequacy of reimbursement for drug administration services. Unless changes are made, many oncologists will face a loss under the buy-and-bill model, a loss that will be even *greater* should they opt to participate in CAP. This is because the only reimbursement they will receive under CAP is payment for drug administration services – which will fall well below the cost of providing drug administration services.

In light of the reimbursement shortfall that looms on January 1, 2006, many cancer care specialists will face a very different choice than the one that Congress intended: continue to offer cancer care services to seniors (under buy-and-bill or CAP) and incur a significant net loss...or discontinue offering chemotherapy services to Medicare beneficiaries altogether. Sadly, both approaches threaten the community cancer care services on which millions of Americans now depend.

Congress has clearly stated its intent that patient access to community cancer care must be preserved because it is the source of convenient, cost-effective care for more than 4-out-of-5 American cancer patients. If CMS intends to abide by this intent, it must take additional steps to align Medicare reimbursement with the cost of drug administration services.

Because the level of needed fee schedule restructuring is significant, CMS may be unable to solve this pending crisis before the 2006 Physician Fee Schedule must be published. As a result, I urge CMS to extend the quality demonstration while it works to match drug administration cost and payments. Otherwise, both the CAP and the ASP models will be doomed to failure and many Medicare cancer patients likely will be forced back to hospitals for chemotherapy.

Issue Identifier: Categories of Drugs To Be Included Under the CAP

The design and implementation of a competitive acquisition program for Part B drugs is an enormous undertaking. It is also an undertaking that will move Medicare into largely uncharted waters. That fact alone argues for a cautious approach.

Although CMS has managed two competitive acquisition demonstration projects for certain types of durable medical equipment, prosthetics and supplies (DMEPOS) in limited geographic markets, it has never organized and run a competitive acquisition program on a national or even a regional scale. The Part B drug CAP differs significantly from the DMEPOS demonstrations because of complicated state licensing and regulatory schemes, the criticality of most of the products involved from a beneficiary perspective, the single-source nature of many of the drugs to be furnished, and the necessity for substantial changes in Medicare claims processing systems that go beyond anything required to implement the DMEPOS demonstrations.

With DME, there were numerous established suppliers operating in a largely unregulated state licensure environment. Because participation in the demonstration by Medicare beneficiaries living in the test areas was mandatory, the bidders knew the size of the potential market. The bidders also ran established businesses and clearly understood the cost structures of those businesses. Unlike the situation with single-source drugs that are the standard of care for many cancer patients today, each product category subject to DMEPOS competitive bidding included numerous items under most HCPCS codes subject to the demonstration. Also unlike the situation that will face manufacturers of Part B drugs in 2006, the discounts extended to DMEPOS competitive bidders did not impact Medicare reimbursement for the manufacturer's product in locations outside the demonstration area. In other words, with DMEPOS, CMS could count on an adequate supply of qualified bidders positioned to put forth bids consistent with required quality and service standards without

sacrificing reasonable profitability and jeopardizing solvency. Furthermore, the product categories included in the DMEPOS demonstrations are not generally seen as carrying the same level concern about product integrity or medical errors as do Part B drugs. Therefore, if DMEPOS CAP vendors stinted on quality or service, the likely outcome for beneficiaries was not as potentially significant as if problems develop with the Part B drug CAP.

The GAO Issued a final report to Congress assessing the DMEPOS demonstrations in September 2004. In that report, the GAO suggested that CMS consider conducting more competitive bidding demonstrations for items and services not in the original demonstrations prior to the beginning of the MMA-mandated implementation of CAP for DMEPOS.

This suggestion argues for taking a slow approach to the Part B drug CAP. In fact, it appears that CMS may already agree. In its final report on the DMEPOS CAP demonstration projects, CMS observed "one of the benefits of conducting demonstrations projects is the ability to learn from the demonstration and apply the lessons if the demonstration is adopted on a wider scale."

Instead of diving into a national CAP involving all Part B drugs used in "incident to" services, CMS should begin with a regional or national test involving a limited set of drugs that are typically administered by a physician specialty that uses drugs less intensely than oncology. This would allow CMS to refine its application and vendor selection procedures and its quality and service requirements, correct glitches in CAP upgrades to its claims processing systems, work out handling issues stemming from state regulations, assess and adjust for changes in practice expenses attributable to CAP, and complete the work needed to better match the reimbursement rates for drug administration services to actual costs for the various specialties before CAP is implemented more universally.

Issue Identifier: Competitive Acquisition Areas

I believe that the proposed timelines for routine and emergency delivery are inadequate and that vendors must be required to make routine deliveries anywhere in their service area within 24-hours of a practice's submission of a new prescription 7 days a week. I base this recommendation on three principle considerations. First, it is not unusual for oncology practices to operate 6 and 7 days a week to meet their patients' needs. Second, it is estimated that approximately one-third of treatment plans must be modified on the day of treatment due to changes in a patient's health status. Third, the unavailability of drugs needed on the day of treatment would pose a significant burden on patients who would have to return another day for treatment. This burden can be particularly severe in rural areas were patients may have to travel long distances to receive cancer care.

CMS has the authority to require that CAP vendors be able to deliver drugs within 24 hours 7 days a week under the statutory language in Social Security Act §1847B(b)(2)(A)(i)(II). That provision imposes two standards on CAP vendors: the ability to make timely deliveries and the ability to ship *at least* 5 days each week. I believe that CMS should use its authority to define "timely delivery" as a 24-hour turn around and 7-day-a-week delivery services. I fear that anything less could jeopardize the ability of cancer care specialists to meet their patients' clinical needs.

I believe CMS should not rely on an expectation that oncologists who choose CAP will continue to maintain an adequate inventory of drugs that can be used to treat Medicare patients in emergencies under the inventory replacement provisions of the CAP rule. CAP is expected to spur growth in commercial payers' mandatory vendor imposition (MVI) programs. As a result, some physicians who elect CAP and continue offering in-office drug administration services may cease to maintain any on-site drug inventories. Even those

practices that maintain inventories may limit them for a variety of reasons, including differences in the clinical needs of their Medicare and non-Medicare patient bases.

Finally, I note that neither the changes to 42 CFR 414.902 set forth in the proposed rule nor the text of the existing regulation define the term "emergency." It is essential for the definition of emergency to be clearly set forth in the final rule and not left to the discretion of each CAP vendor or to the discretion of local carriers tasked with adjudicating practices' claims for drug administration services. Moreover, the definition should turn on the treating physician's clinical judgment that patient health would suffer from delay in treatment, not on the CAP vendor's or the local carrier's remote assessment of the situation.

Issue Identifier: Claims Processing Overview

I am concerned that the proposed rule's delivery standards could pose a significant risk of increased financial and clinical costs to cancer patients. Today, cancer care practices routinely maintain a drug inventory to meet their patients' treatment needs. This has enabled practices to accommodate changes in patients' treatment plans without requiring the patient to return for therapy on another day. Under CAP, however, this level of service could be difficult if not impossible to maintain.

If chemotherapy sessions must be rescheduled to wait for the delivery of the drug(s) that patients need, they will face additional coinsurance obligations for the repeat physician services. In addition, patients will face other financial burdens in the form of higher transportation costs and additional missed time from work. This situation may also mean missed work time and reduced productivity for family members and other caregivers who must bring beneficiaries to the rescheduled treatment sessions.

I recognize that Social Security Act 1847B(b)(5) and the proposed rule permit physicians to receive replacement product from their CAP vendors for drugs taken from the physician's inventory. Even if CAP physicians had a sufficient inventory to draw from, this option appears too narrowly tailored to save most patients from having to undertake a return trip and bear the cost of an additional coinsurance payment. Specifically, the use of the replacement program is limited to situations where the physician builds a record to demonstrate all of the following to the local carrier: (1) the drugs were required immediately, (2) the physician could not have anticipated the patient's need for the drugs, (3) the CAP vendor could not deliver the drugs in a timely manner, and (4) the drugs were administered in an emergency situation.

There are a few glaring problems with the inventory replacement option. First, neither the statute nor the proposed rule defines "emergency." Moreover, neither the proposed rule nor the preamble discussion explains what a physician would have to show to justify immediate need or how the local carrier will assess whether the physician could have anticipated the patient's drug needs sufficiently far in advance to permit delivery via the CAP vendor. Aside from the risk that the claim for replacement drug will be denied by the local carrier, the administrative burden of building this record may discourage many physicians from using the inventory replacement option. The inventory replacement option also raises the question about whether commercial insurers are being asked to subsidize a portion of the drug costs for Medicare beneficiaries in CAP, since Medicare would not be paying a physician for the ordering, financing, inventorying and handling costs associated with drugs borrowed from the practice's inventory.

I am even more concerned about what this option could mean for patients, since it is not at all clear that oncology practices will be able to maintain full inventories after the implementation of CAP. Depending on their patient bases, the range of drugs that some practices would need for Medicare beneficiaries may not be the same as the drug inventory that the practice would stock for commercial patients. Moreover, if CAP encourages the

proliferation of mandatory vendor imposition (MVI) programs among commercial carriers, it is likely that some practices may stop maintaining drug inventories altogether.

In sum, patients may be forced to pay both a financial and clinical price for treatment disruptions due to CAP, potentially exposing them to medical complications and increased emergency hospitalizations in addition to repeat visits and higher cost-sharing obligations.

Issue Identifier: Claims Processing Overview
Dispute Resolution

According to the preamble to the Proposed Rule, CMS believes that CAP will not significantly increase the administrative burden on physicians. As a result, CMS has concluded that the payment for clerical and inventory management services that is bundled into the drug administration codes should be adequate to cover the practice expenses which physicians will occur under CAP. This is unrealistic for a number of reasons, including the following:

First, CAP practices will have to implement and operate a second, separate ordering process for CAP drugs to transmit patient-specific drug orders that include demographic and clinical information. The ordering system under the buy-and-bill model is much simpler because aggregate orders based on practice usage are placed with wholesalers. Buy-and-bill ordering does not involve the review of individual patient charts nor does it require input of substantial amounts of data for each vial of drug requested from the wholesaler.

Second, CAP will increase the demands on oncology practices for pharmacy management services. Changes in individual treatment plans will have to be closely monitored so that new prescriptions can be sent to the vendor in timely fashion. The job of ensuring that drugs are given to the right patient and that patient-specific drug supplies provided in multi-dose vials have not expired or passed stability deadlines before the entire vial is used will be more complicated because the time that any particular multi-dose vial must be maintained and monitored will increase. The increases in complexity of required pharmacy management services will also increase the risk of medication errors.

Since the current level of pharmacy services costs is not captured in the practice expense component of payments for drug administration services, the new costs imposed by CAP will be both additive and uncompensated.

Third, CAP will likely increase hazardous waste disposal costs substantially due to complications regarding the redirection, in the physician's office, of unused drug dispensed for one patient to another patient. Waste handling costs will also be higher under CAP due to the increased likelihood that a drug designated for a particular patient will pass its expiration or stability deadline before the entire vial can be finished. As a result, total waste quantities could quickly exceed levels allowable for routine disposal, thereby adding even greater costs.

Fourth, CAP physicians will face much higher claims administration costs. CAP requires Medicare claims for drug administration services to be filed within 14 days of the drug administration service. This represents an increased burden since the Proposed Rule acknowledges that only about 75% of claims currently are filed within this timeframe and since claims processing software will need to be upgraded. Further, CAP physicians will be unable to make a cost-benefit decision about the value of appealing a claim denial for drug administration services. Instead, physicians could be forced to appeal all denials in a process that requires all the evidence needed to support the appeal to be collected and submitted.

Issue Identifier: Contracting Process – Quality and Product Integrity Aspects

In an effort to ensure the stability of CAP, MMA directs CMS to require CAP vendors to meet standards for quality, service, financial performance and solvency that include appropriate procedures for the resolution of physician complaints and grievances. Unfortunately, the statute offers few specifics regarding these standards, and the proposed rule does not define all of the standards to which the vendors will be held. As it has done in the DMEPOS Supplier manuals, CMS should issue CAP guidance that defines measurable quality, service, financial performance and solvency standards.

I am concerned about the administrative burden on physician practices that will result from the CAP Election Agreement's requirement that physicians appeal all denied drug administration claims.

Physicians are not entitled to any reimbursement for administrative costs incurred as a result of participation in the CAP program.

- Submit a written order or prescription to the CAP vendor
- supply information to the CAP vendor to facilitate collection of applicable beneficiary liability, Notify the CAP vendor when a drug is not administered,
- Maintain a separate electronic or paper inventory for each CAP drug obtained
- File the Medicare claim within 14 days of the date of drug administration
- Appeal a denied claim and submit all documentation necessary to support payment

The burden of appealing every denied drug administration claim is heightened by the pending changes in the claims appeal process that become effective on May 1, 2005. Given the magnitude of those changes, CMS should require the CAP vendor to request clinical literature from drug manufacturers needed to support appeals of drug administration denials.

I am also concerned that the proposed rule ignores the significant risk that physicians could face litigation over adverse drug events due to drugs provided by a CAP vendor. I strongly urge CMS to require CAP vendors to indemnify physicians for all costs, including reasonable attorney's fees, associated with the defense of all such actions where the physician is ultimately exonerated.

The proposed rule does not specify how CMS will ensure ongoing compliance with vendor performance requirements, so CMS should issue a detailed guidance document, require CAP vendors to report key performance statistics quarterly, and consider imposing contractually defined financial penalties for sub-par performance in addition to the imposition of False Claims Act liability that vendors face.

Issue Identifier: CAP Bidding Process – Evaluation and Selection

CMS intends to contract only with qualified CAP bidders that submit composite bids with a weighted average price per HCPCS unit that is no greater than 106% of the weighted ASP for the drugs in the category. Reimbursement at 106% of ASP is inadequate to cover physicians' costs for chemotherapy drugs and for pharmacy management services and other associated expenses, including bad debt, that are currently not considered in the practice expense component of the drug administration G codes.

Just as I believe this level of reimbursement is inadequate for physicians under the buy-and-bill model, so too do I view reimbursement at 106% of ASP to be inadequate under the CAP model. Competition will not cause manufacturers of most single-source drugs to discount their products to CAP vendors or to any other class of buyer that must be considered when Best Price is calculated. And, like physician practices nationwide, bad debt will pose a major financial challenge to CAP vendors.

In addition, CAP vendors will incur significant middleman costs, including administrative, dispensing, shipping, product disposal, and bad debt costs. These costs are borne by physician practices everyday, but CAP vendors will likely face even greater difficulty collecting due to the time delay between the dates of treatment and payment, as well as their lack of a direct relationship with patients. Beneficiaries who are already contending with deductibles and coinsurance payments not covered by secondary insurance, travel expenses, custodial care expenses, costs associated with changed dietary needs, etc., may place a relatively low priority on paying their CAP vendors or chose to forgo treatment.

Just as the absence of personal relationships between beneficiaries and CAP vendors is likely to exacerbate the vendors' bad debt collection problems, I fear it will also exacerbate some vendors' use of overly aggressive collection efforts, including decisions to stop providing drugs for patients who are too far in arrears. The Practicing Physicians Advisory Council has also raised this concern and proposed that CMS address it in the final CAP rule by mandating that vendors advance credit to patients unable to afford their coinsurance payments. CMS should go a step further and ask that the vendors also be required to have in place procedures for assessing indigence and waiving coinsurance when a non-Medicaid-eligible beneficiary's income, assets, and medical expenses meet certain pre-established criteria. Ideally, these procedures should incorporate the assistance of social workers trained to explore all payment options and assistance programs available to the individual.

Unlike the situation with physicians where reimbursement for Part B drugs supplied under the buy-and-bill model is set by statute at 106% of ASP, CMS may have the discretionary authority under Social Security Act §1847B to permit payments to CAP vendors at any level necessary to compensate them fairly and appropriately for their services. It appears that Congress only expected competition under the CAP model to save money on multi-source drug products, not single-source drugs and biologicals.

Pre-defining an unrealistically low reimbursement cap could under-capitalize vendors, resulting in too few qualified bidders, the provision of improper services, and patient harm. Therefore, CMS should either abandon the notion that CAP will save money in the aggregate for Medicare Part B or phase in the program slowly by starting with a small group of drugs or with a specialty that does not use "incident to" drugs intensively to test the impact of an potentially under-reimbursed CAP model on beneficiary access to care and on the robustness and financial viability of the CAP vendor market.

In either case, one conclusion should be recognized: just as 106% of ASP is too low in the buy-and-bill model, so too is it unsustainable in CAP.

Issue Identifiers: Contract Requirements

The World Health Organization estimates that 6% of all drugs distributed in the world are counterfeit and some observers believe it to be as high as 12%. Since most counterfeit drugs in the US enter the chain of commerce through the secondary market, I applaud Congress' decision to require CAP vendors to acquire all of their drugs directly from the manufacturer or from a wholesaler that buys direct.

Product integrity is about more than blocking the distribution of counterfeit goods, however. That is why I am concerned that the Proposed Rule's provisions could jeopardize product integrity and violate state licensing laws.

I suspect that CMS may not have thought through licensing and product integrity issues because it seems to have concluded that CAP vendors should be licensed as wholesalers but not as pharmacies. Indeed, many provisions in the Proposed Rule and the entire discussion of product integrity in the preamble focuses on wholesale distributors.

I am convinced that CAP vendors must be licensed as pharmacies, however. The statute does not expressly define the class of trade of a CAP vendor and §1847B(b)(4)(C) could suggest that Congress viewed CAP vendors as wholesalers. And yet, Social Security Act §1847B(b)(6) seems to take a different position, stating that nothing in Social Security Act §1847B "shall be construed as waiving applicable State requirements relating to licensing of pharmacies."

CAP vendors must be licensed as pharmacies because they will accept patient-specific written orders for prescription drugs from physicians, assign prescription numbers to those orders, interpret the orders, presumably making generic substitutions as appropriate and permissible under applicable State law, and then transfer dispensed drugs to the prescribing physician for administration to the patient. This patient-specific transfer amounts to "dispensing" a drug under state pharmacy practice acts and because CAP vendors dispense, they are practicing pharmacy and must be licensed accordingly.

Since CAP vendors must operate as licensed pharmacies, some of the operational aspects of CAP seem unworkable or in need of retooling. For example, state pharmacies laws do not permit a pharmacist to assign different prescription numbers to successive fills of a single prescription. Rather, prescription refills are always dispensed under the prescription number assigned to the original written order. A new prescription number is assigned only when a new written order is received. These practices are inconsistent with the prescription numbering system described in the preamble to the Proposed Rule.

Another critical problem is posed by CMS's proposal for dealing with CAP drugs that cannot be administered to the beneficiary for whom they were prescribed. Most state pharmacy laws prohibit the restocking of unused drugs after they have been dispensed. By establishing a process for the restocking and use of previously-dispensed drugs, however, the proposed rule appears to put the physician in the position of aiding and abetting the violation of these state pharmacy laws. In fact, none of the laws of which I am aware allow dispensed product to be redirected to another patient without going back to the dispensing pharmacy first.

Redirecting unused drugs dispensed by a CAP vendor from the intended recipient to another patient could expose physician practices to tort liability. Physicians participating in CAP will therefore need indemnification from CAP vendors when reuse decisions about drugs belonging to the vendor, not the physician, are made based on discussions with the CAP pharmacist. CMS should build requirements for appropriate indemnities into the final rule.

Issue Identifier: Physician Election Process

Social Security Act §1847B(a)(1)(A)(ii) states that *each physician* may select between the buy-and-bill model and the CAP model on an annual basis. Further, §1847B(a)(1)(A)(iii) requires that *each physician* selecting the CAP option be given the opportunity to pick the CAP vendor of his or her choice. CMS's apparent decision to make the choice between the buy-and-bill model and the CAP model a group practice decision rather than a physician-specific decision is contrary to the plain language of the statute. It is also inconsistent with Congress' stated intent that the choice of CAP should, as stated in the Conference Report, "be completely voluntary on behalf of *the* physician."

CMS has justified its decision to make the choice between buy-and-bill and CAP a group practice choice by saying that Social Security Act §1847B(a)(5)(A) "requires that we coordinate the physician's election to participate in the CAP with the Medicare Participating Physician Process described in section 1842(h) of the Act." That is not quite right. What §1847B(a)(5)(A)(ii) actually requires is that "[t]he *selection of a [CAP] contractor* . . . shall be coordinated with agreements entered into under section 1842(h)."

Instead of reading the statutory requirement to "coordinate" the CAP vendor selection process with the Medicare Participating Physician Process simply as a directive to minimize paperwork by aligning the two selection processes in time and utilizing the same form for both, CMS has taken a very different tack. In so doing, it has converted the CAP selection process into a group practice decision and effectively eliminated the option of individual physician decision-making about CAP required by the statute and intended by Congress.

In some instances, physicians in group practices will be unable to come to agreement about the choice between the buy-and-bill model and the CAP model. Some physicians feel strongly about the risks to product integrity under CAP because of problems with counterfeit drugs experienced under commercial insurer MVI programs. Others are concerned about the potential impact on beneficiary access if CAP vendors are permitted to "cut off" patients who fail to make timely coinsurance payments. Still others simply do not see how they can afford the increased administrative burden and increased drug-handling costs expected under CAP.

These types of concerns will be difficult to resolve and could result in situations where the CAP question causes practices to dissolve.

CMS has offered an unsatisfactory "solution" to address the statutory requirement for individual physician choice: if the "physician in the group practice also has a solo practice, he or she may make a different determination to participate or not to participate in the CAP when using his or her individual PIN." In fact, this seems to invite groups that cannot agree on the CAP issue to break apart to preserve each camp's ability to qualify as a group practice under the Stark Law. Although the provision of "incident to" drugs furnished by a CAP vendor presumably will not trigger the Stark Law since a practice will have no financial stake in the outpatient prescription drugs, many group practices rely on the in-office ancillary service exception for purposes beyond drug treatment and would have legitimate concerns about the implications of a partial break-away of group members under the "substantially all test" used to define group practices.

I recognize that CMS's claims processing systems are set up based on group numbers and that carriers may need to implement system changes to deal with individual choice. And yet, I also recognize that the statute, the Conference Report, and even statements made by the CMS Administrator all share one crucial theme: participation in CAP will be a physician's completely voluntary choice. Denying the right of individual choice simply to avoid system upgrades is unfounded and unacceptable.

Because the level of needed fee schedule restructuring is significant, CMS may be unable to solve this pending crisis before the 2006 Physician Fee Schedule must be published. As a result, I urge CMS to extend the quality demonstration while it works to match drug administration cost and payments. Otherwise, both the CAP and the ASP models will be doomed to failure and many Medicare cancer patients likely will be forced back to hospitals for chemotherapy.

Sincerely,

Amy S. King
Practice Manager
Nebraska Hematology-Oncology, PC
2611 South 70th Street
Lincoln, NE 68506

Submitter : Dr. Gail Wright **Date:** 04/13/2005

Organization : Florida Cancer Institute

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

As a physician I am responsible for the medications administered in my office. I cannot ensure the quality control of medications sent to us by an outside vendor that has no responsibility to our organization. We know what quality control measures are in place with our own acquisition mechanism and our own pharmacists. We all are aware of examples of counterfeit drugs as well as one well publicized example of intentional underdosing of chemotherapy for profit. Chemotherapy and biologicals are too critical in terms of both risks (toxicities) and benefits to be held responsible but not have this degree of control. I am strongly opposed to this competitive acquisition program.

Submitter : Mr. James Limoli

Date: 04/13/2005

Organization : Pathways, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-104-Attach-1.DOC

CMS-1325-P-104-Attach-2.DOC

Pathways, Inc.
7350 Palisades Parkway
Mentor, Ohio 44060
440-918-1000
440-918-1029 Fax

April 14, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Part B Competitive Acquisition Program, Categories of Drugs to be Included under CAP

Dear Dr. McClellan:

I am writing in strong support of the proposed rule recently issued by the Centers for Medicare and Medicaid Services (CMS) that addresses implementation of the Competitive Acquisition Program (CAP). This program has tremendous potential to benefit individuals with severe and persistent mental illnesses for whom injectable medications can help maintain adherence to drug regimens, treatment that is life-saving and essential to successful rehabilitation outcomes. We urge that injectable antipsychotic medications be included in the initial phase of CAP implementation.

Advantages of Injectable Psychiatric Medications

In 2003, the final report of the President's New Freedom Commission on mental health declared that recovery – helping individuals overcome the disabling aspects of mental illnesses – is the overarching goal of the U.S. mental health system. Addressing the means for attaining this goal, the report stated, " To achieve the promise of community living for everyone, new service delivery patterns and incentives must ensure that every American has easy and continuous access to the most current treatments and best support services." In implementing the CAP program, CMS has an opportunity to make a significant contribution to fulfilling the goals of the federal New Freedom Initiative by facilitating patient access to important psychiatric medications.

Patient noncompliance with psychotropic medication regimens is similar to that for patients who take medications for somatic illnesses. A review of the literature has found that most patients probably only take 33 – 94 percent of their prescribed drugs, with the median being about 50 percent for long-term therapy, while a

sizeable percentage are wholly noncompliant.[1] For people with schizophrenia and severe mood disorders, noncompliance with medications often results in the relapse of acute symptoms, frequently resulting in negative outcomes such as rehospitalization, loss of employment/housing, and suicide. These negative consequences for the patient are compounded by a parallel negative impact on the service delivery system: costs escalate as outpatient treatment is stymied, the use of emergency facilities increases, and hospital stays are more frequent and longer.

The use of injectable antipsychotics has been recognized as an important, evidence-based practice that addresses the noncompliance of issue of many with schizophrenia. In addition, a new type of psychotropic medications show tremendous promise in addressing the issue of partial compliance among people with mental illnesses. These new medications are injectable, but do not have the side effect profile of older injectable depot psychotropics that consumers found objectionable, including lingering pain after the injection, sedation, and other effects. While a number of the new injectable medications are currently in development (including an antidepressant), one antipsychotic, an injectable form of risperidone, has been employed successfully in community-based settings for about a year, and it has shown great promise in treating schizophrenia.

The Schizophrenia Patient Outcomes Research Team (PORT) treatment recommendations, considered one of the most important practice guidelines for the treatment of schizophrenia, find that the older injectables are an important therapy for schizophrenia, stating that depot injectables should be "strongly considered for persons who have difficulty complying with oral medication..." The emerging evidence for the use of risperidone long-acting injection seems to indicate that the new injectable antipsychotics may offer significant clinical advantages to the older depot injectables, in addition to addressing the issue of noncompliance. Compliance is a significant issue in the treatment of schizophrenia, with 50 – 70 percent of all patients being only partially compliant in the first two years of treatment. A survey of studies found that noncompliance was associated with a risk of relapse that is 3.7 times greater than that for compliant patients.[2]

Studies have found that use of long-acting injectable risperidone is associated with fewer and shorter hospitalizations[3] and improved functioning and quality of life.[4] Given the promise of these new injectable medications to improve outcomes for patients and reduce healthcare costs, and the recognition of the use of injectable depot medications as an evidence-based practice, we believe that CMS should make consumer access to injectable antipsychotic medications an urgent priority. As other new injectable psychotropics become available, we suggest that CMS prioritize efforts to enhance consumer access to these drugs.

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Current Obstacles Faced by Providers Using Injectable Psychiatric Medications

Unfortunately, community mental health centers (CMHCs) and other multi-service community providers, which serve a large number of people with severe mental illnesses that are eligible for both Medicaid and Medicare, face serious obstacles in providing injectable medications. As safety-net providers, CMHCs are very often heavily burdened treatment settings that lack sophisticated information technology and a sufficient level of administrative staffing. For example, to provide the new injectable antipsychotic risperidone to patients, CMHCs must first purchase the medication, and then seek reimbursement from both Medicare (which makes only partial payment for mental health drugs) and Medicaid. Providers then bear the administrative burden of tracking the claims and the financial risk of receiving incomplete payment from one or both payers. This burden has become an impediment to expanding access to this medication to the full range of patients who could benefit from it. In some cases, CMHCs will only provide the medication to patients that are solely Medicaid beneficiaries. When injectable antipsychotics are included in the Medicare CAP program, this substantial impediment will be removed, as providers would have the option to obtain the medications from a drug vendor that will handle reimbursement from Medicare. Helping providers expand access to this medication will bring great benefit to our patients with schizophrenia.

From a brief review of the proposed rule, it appears that CMS may view oncology medications as the primary medication category to be included in the initial phase of CAP. CAP also has the potential to bring new psychiatric therapies into wider use and to significantly improve the quality of care for some of the most vulnerable people in our society – helping to "achieve the promise" of the New Freedom Initiative for people with psychiatric disabilities. We urge you to include coverage of antipsychotic injectable medications in the drug categories that compose the initial phase of CAP implementation.

Sincerely,

James Limoli
CEO
Pathways, Inc.

Pathways

Pathways, Inc.
7350 Palisades Parkway
Mentor, Ohio 44060
440-918-1000
440-918-1029 Fax

April 14, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Part B Competitive Acquisition Program, Categories of Drugs to be Included under CAP

Dear Dr. McClellan:

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Advantages of Injectable Psychiatric Medications

In 2003, the final report of the President's New Freedom Commission on mental health declared that recovery – helping individuals overcome the disabling aspects of mental illnesses – is the overarching goal of the U.S. mental health system. Addressing the means for attaining this goal, the report stated, " To achieve the promise of community living for everyone, new service delivery patterns and incentives must ensure that every American has easy and continuous access to the most current treatments and best support services." In implementing the CAP program, CMS has an opportunity to make a significant contribution to fulfilling the goals of the federal New Freedom Initiative by facilitating patient access to important psychiatric medications.

Patient noncompliance with psychotropic medication regimens is similar to that for patients who take medications for somatic illnesses. A review of the literature has found that most patients probably only take 33 – 94 percent of their prescribed drugs, with the median being about 50 percent for long-term therapy, while a

sizeable percentage are wholly noncompliant.[1] For people with schizophrenia and severe mood disorders, noncompliance with medications often results in the relapse of acute symptoms, frequently resulting in negative outcomes such as rehospitalization, loss of employment/housing, and suicide. These negative consequences for the patient are compounded by a parallel negative impact on the service delivery system: costs escalate as outpatient treatment is stymied, the use of emergency facilities increases, and hospital stays are more frequent and longer.

The use of injectable antipsychotics has been recognized as an important, evidence-based practice that addresses the noncompliance of issue of many with schizophrenia. In addition, a new type of psychotropic medications show tremendous promise in addressing the issue of partial compliance among people with mental illnesses. These new medications are injectable, but do not have the side effect profile of older injectable depot psychotropics that consumers found objectionable, including lingering pain after the injection, sedation, and other effects. While a number of the new injectable medications are currently in development (including an antidepressant), one antipsychotic, an injectable form of risperidone, has been employed successfully in community-based settings for about a year, and it has shown great promise in treating schizophrenia.

The Schizophrenia Patient Outcomes Research Team (PORT) treatment recommendations, considered one of the most important practice guidelines for the treatment of schizophrenia, find that the older injectables are an important therapy for schizophrenia, stating that depot injectables should be "strongly considered for persons who have difficulty complying with oral medication..." The emerging evidence for the use of risperidone long-acting injection seems to indicate that the new injectable antipsychotics may offer significant clinical advantages to the older depot injectables, in addition to addressing the issue of noncompliance. Compliance is a significant issue in the treatment of schizophrenia, with 50 – 70 percent of all patients being only partially compliant in the first two years of treatment. A survey of studies found that noncompliance was associated with a risk of relapse that is 3.7 times greater than that for compliant patients.[2]

Studies have found that use of long-acting injectable risperidone is associated with fewer and shorter hospitalizations[3] and improved functioning and quality of life.[4] Given the promise of these new injectable medications to improve outcomes for patients and reduce healthcare costs, and the recognition of the use of injectable depot medications as an evidence-based practice, we believe that CMS should make consumer access to injectable antipsychotic medications an urgent priority. As other new injectable psychotropics become available, we suggest that CMS prioritize efforts to enhance consumer access to these drugs.

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From a brief review of the proposed rule, it appears that CMS may view oncology medications as the primary medication category to be included in the initial phase of CAP. CAP also has the potential to bring new psychiatric therapies into wider use and to significantly improve the quality of care for some of the most vulnerable people in our society – helping to "achieve the promise" of the New Freedom Initiative for people with psychiatric disabilities. We urge you to include coverage of antipsychotic injectable medications in the drug categories that compose the initial phase of CAP implementation.

Sincerely,

James Limoli
CEO
Pathways, Inc.

Submitter : Dr. Daniel B. Martinez **Date:** 04/13/2005

Organization : Pilsen-Little Village Community Mental Health Cent

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

We can mental health parity. The U.S. needs mental health as a therapeutic category in the competitive acquisition program. Medications, like Risperdal Consta, should be covered in this acquisiton program. We need these mental health drugs to be considered from day one. Time, energy, resources are scarce in the service delivery to psychiatrically ill patients. Community mental health agencies are having a difficult time staying afloat. We need to minimize barriers to patient access for therapies, particularly the non-self-administered therapies.

Submitter : Ms. Renee Kilroy

Date: 04/13/2005

Organization : Suncoast Center for Community Mental Health, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-106-Attach-1.DOC

CMS-1325-P-106-Attach-2.DOC

April 14, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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Sincerely,

Renee' Kilroy
Director, Adult Services
Suncoast Center for Community Mental Health, Inc.

April 14, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
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Washington, D.C. 20201

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[3] Leal A, Rosillon D, Mehnert A et al. Healthcare resource utilization during 1-year treatment with long-acting injectable risperidone, Pharmacoepid Drug Safety, 2004, 13: 811-816.

[4] Nasrallah HA, Duchesne I, Mehnert A, et al. Health-related quality of life in patients with schizophrenia during treatment with long-acting injectable risperidone. J Clin Psychiatry 2004, 65:531-536.

partial payment for mental health drugs) and Medicaid. Providers then bear the administrative burden of tracking the claims and the financial risk of receiving incomplete payment from one or both payers. This burden has become an impediment to expanding access to this medication to the full range of patients who could benefit from it. In some cases, CMHCs will only provide the medication to patients that are solely Medicaid beneficiaries. When injectable antipsychotics are included in the Medicare CAP program, this substantial impediment will be removed, as providers would have the option to obtain the medications from a drug vendor that will handle reimbursement from Medicare. Helping providers expand access to this medication will bring great benefit to our patients with schizophrenia.

From a brief review of the proposed rule, it appears that CMS may view oncology medications as the primary medication category to be included in the initial phase of CAP. CAP also has the potential to bring new psychiatric therapies into wider use and to significantly improve the quality of care for some of the most vulnerable people in our society – helping to "achieve the promise" of the New Freedom Initiative for people with psychiatric disabilities. We urge you to include coverage of antipsychotic injectable medications in the drug categories that compose the initial phase of CAP implementation.

Sincerely,

Renee' Kilroy
Director, Adult Services
Suncoast Center for Community Mental Health, Inc.

Submitter : Mr. John Walker **Date:** 04/13/2005

Organization : Pennyroyal MH/MR regional Board, Inc.

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

As Associate Executive Director of Clinical Operations for a Regional Mental Health Center that is the primary provider for the indigent and disabled population I am requesting that CMS use its discretionary authority and include "Psychiatric Drugs" in phase I. This is important since these medications when available to the clients are useful in reducing hospitalizations and keeping these individuals functional in the community. This places a much smaller burden on the public resources and will make medications available that otherwise would be out of the financial ability of this class of client.

CMS would be providing a great service by including in Part B, mental health medications, including the "long-acting injectable antipsychotics.

On behalf of our Psychiatrists, ARNP, Nurses, Clinical staff, Case Managers and the clients, I want to thank you for the opportunity to speak in support of expanding this coverage to psychiatric medications.

John O. Walker, LCSW

Submitter : **Dr. Burton Alexander** **Date: 04/13/2005**

Organization : **Virginia Oncology Assoc**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Issue Identifier: Overview of CAP

In its implementation of the Medicare Modernization Act of 2003 (MMA), the Centers for Medicare and Medicaid Services (CMS) has sought to more adequately cover the labor, supply, pharmacy, and other costs incurred in the administration of cancer-fighting drugs. Among the steps taken is the adoption of G codes to cover drug administration services and the creation of a demonstration project for 2005 that provided additional reimbursement.

As a result, 2005 Medicare reimbursement for cancer care services is considerably higher than pre-MMA rates. However, total reimbursement will drop dramatically on January 1, 2006, when the demonstration project is scheduled to end and the drug administration transitional factor will be zeroed out.

It has been calculated that the impact of these changes will translate into a $940 underpayment for drug administration services per Medicare beneficiary. Put another way, 2006 Medicare reimbursement for patient care services will cover only an estimated 50.09% of drug administration costs.

This problem is a key factor in the implementation of the Competitive Acquisition Program (CAP) in 2006. Under CAP, middlemen vendors will furnish drugs to physicians who choose to give up the traditional buy-and-bill model and select the CAP model instead. The vendors will be responsible for billing Medicare for the drugs, and the physicians will receive reimbursement only for drug administration services.

CMS expects CAP to appeal to those physicians ?who do not want to be in the drug procurement and drug coinsurance collection business? [70 Fed. Reg. 10750]. Indeed, statements made by CMS and CAP?s Congressional authors all reinforce the notion that CAP is intended to be an option that physicians may choose to adopt in place of the current buy-and-bill model. According to the MMA Conference Report produced by Congress, ?Conferees intend this choice to be completely voluntary on behalf of the physicians? [H. R. Conf. Rep. No. 108-391, 108th Cong., 1st Sess. 593 (2003)].

And yet, it is possible that neither CMS nor Congress has recognized that the viability of these two choices turns on the adequacy of reimbursement for drug administration services. Unless changes are made, many oncologists will face a loss under the buy-and-bill model, a loss that will be even greater should they opt to participate in CAP. This is because the only reimbursement they will receive under CAP is payment for drug administration services ? which will fall well below the cost of providing drug administration services.

In light of the reimbursement shortfall that looms on January 1, 2006, many cancer care specialists will face a very different choice than the one that Congress intended: continue to offer cancer care services to seniors (under buy-and-bill or CAP) and incur a significant net loss?or discontinue offering chemotherapy services to Medicare beneficiaries altogether. Sadly, both approaches threaten the community cancer care services on which millions of Americans now depend.

Congress has clearly stated its intent that patient access to community cancer care must be preserved because it is the source of convenient, cost-effective care for more than 4-out-of-5 American cancer patients. If CMS intends to abide by this intent, it must take additional steps to align Medicare reimbursement with the cost of drug administration services.

Because the level of needed fee schedule restructuring is significant, CMS may be unable to solve this pending crisis before the 2006 Physician Fee Schedule must be published. As a result, I urge CMS to extend the quality demonstration while it works to match drug administration cost and payments. Otherwise, both the CAP and the ASP models will be doomed to failure and many Medicare cancer patients likely will be forced back to hospitals for chemotherapy.

Submitter : Dr. elizabeth delesante **Date:** 04/14/2005

Organization : Dr. elizabeth delesante

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I support mental health inclusion in the CAP. This will improve patient access. Now medication such as Risperdal Consta, an atypical injectable longacting antipsychotic are VERY difficult to obtain for medicare patients. Many Minnesota clinics do not offer this valuable option to patients because of the cumbersome and expensive buy and bill requirement. This then keeps people from the best practice treatment because of system issues. For those patients who have regular pharmacy coverage for this product it is a simple process of ordering the medication and administering it.Having the injectable covered thru this system would improve patient access nationwide. This helps our local patients because some are snowbirds and travel with their family south for the winter. The buy and bill system DOES NOT let them do this. They are limited to remain to continue treatment. It also presents problems if people move and the new clinic does not or cannot manage a buy and bill system.

Submitter : Dr. Dayna McCauley **Date:** 04/14/2005

Organization : Long Island Gynecologic Oncologists, PC

Category : Physician

Issue Areas/Comments

1-15

Competitive Acquisitions Areas

I beleive this program would only work in state or local competitive acquistion areas, unless the regional or national vendors had enough satellite offices that they could assure timely delivery. If the vendors were restricted to regions, the telephone volume/prescription input to a region could be untennable to keep up with, even if the vendor was experienced. Having some key contact designated for offices within regions/states would also be critical. It is not feasible to expect offices to answer critical questions about dosing and drug delivery for these toxic compounds by going through a 1-800 phone tree mess and speaking to different people all the time.

Overview of the CAP

Realistically, it is impossible to invision a program that works well for a stable, carve out patient population (e.g., CAP and cystic fibrosis) working well for a diverse, unstable patient population (cancer patients). Their disease status changes frequently. Programatically, it is difficult to envision how the CAP structure could responsd to frequent disease status changes without compromising patient care.

Claims Processing Overview

If the processing of claims and obtaining authorization and payment from patients is placed on the vendor, then the physician should absolutely not be responsible for processing claims appeals for denials. We do this now, but in a very tightly controlled environment whereby our staff preauthorizes every treatment. We do not allow therapies to be administered until insurance coverage and/or patient payment has been arranged. The vendor should assume this same responsiblity. If the drug is not covered, the physician should be notified ahead of time and drug administration denied.

Bidding Entity Qualifications

These are reasonable qualifications. I don't know how many vendors can acually meet all these requirements. I would suspect there are very few. If that is the case, then expansion to all regions in the country would prove problematic. The requirement regarding direct manufacturer purchase is key. product integrety is a huge issue. our malpractice carriers hold us (physicians) liable. Regarding this issue, I would want indemnification for physicians regarding product integrity for drugs received from vendors.

Categories of Drugs to be Included under the CAP

I recommend limiting the initiation of this program to a small number of drugs or drug initially. Total chaos could ensue attempting to implement the CAP program across the board for all part B Drugs. The system needs to be tested using real senarios, but limit to oncology, and run a trial period with ONE drug to see if its feasible. (e.g., liposomal doxorubicin, or Doxil). The specialty of oncology uses hundreds of drugs and different combinations. This is still too broad of a category. I recommend one specialty, one drug and test accordingly.

Statutory Requirements Concerning Claims Processing

This will add a burden to offices to remember to call a third party if a patient is not treated. Currently, drugs are not made if a patient is pending treatment or status is unknown. I believe that there will be a significant number of instances when offices will be busy and forget to notify the vendor of treatment changes/delays, etc. It is doable, but quite a bit of extra work.

Contracting Process-Quality and Product Integrity Aspects

This is the key issue. The contracting process as outlined is reasonalbe. what is not, is expecting high quality and product integrity for the lowest possible price (lowest of five bids). Staff trained to work in vendors like Your are proposing are very difficult to find/train/keep. The vendors that have accomplished this probably pay their staff more and are therefore subject to a more expensive product.

GENERAL

GENERAL

General comments: I have significant concerns that this program may actually increase drug waste/cost/. Cancer patients are inherently diverse and clinically unstable. This is a difficult patient population in which to apply a program that requires stability and certainty for proper functioning. It is quite possible that drugs will be ordered/prepared/delivered that are never administered to the patient due to a change in status. How is this wastage accounted for in the contract process? Would the vendor absorb this loss? The other significant concern is the requirement for multiple inventories; patient specific; by carrier, etx. This will be an administrative nightmare in terms of inventory management and storage issues. There is no comment made regarding reimbursement to phsycians for increased medical waste (probable). My third concern is that, as proposed, there is no qualified vendor who would actually want to provide this service. There is incredible burden placed on them under this program. The burden seems impossible to bear. I beleive it is a grave mistake in terms of quality care to separate the drugs from the physician/patient. Perhaps a modification of the buy/bill and CAP could be tried. In this instance, the "first-dose-stat-dose" could be given in the MD office, payable by medicare, with subsequent orders for that treatment sent to the CAP program. This at least would assure the patient timely treatment.

Submitter : Ms. Eileen Hastings **Date:** 04/14/2005

Organization : University of Maryland Medcial Center

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

Submitter : **Mr. James McClaran** **Date: 04/15/2005**

Organization : **NAMI**

Category : **Federal Government**

Issue Areas/Comments

GENERAL

GENERAL

This letter is to express my support for Medicare Competitive Acquisition Program for Part B Drugs. Further, I request that behavioral health/psychiatric drugs be included in this new program beginning in January, 2006. Your attention to this urgent matter will be greatly appreciated. Thank you.

Submitter : Mrs. Betty McClaran **Date: 04/15/2005**

Organization : NAMI

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

I hereby express my support for Medicare Competitive Acquisition Program for Part B Drugs, and request that behavioral health/psychiatric drugs be included in this new program which begins January, 2006. This matter is of utmost importance, and your support will be much appreciated. Thank you.

Submitter : **Mrs. Sharon Killian** **Date: 04/15/2005**

Organization : **Family Member**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

As a daughter of a mentally ill woman on Medicaid and Medicare I ask that you make inclusion of mental health pharmaceuticals part of the initial phase of MMA 2006. Without these drugs, the states and the federal government will pay higher costs for hospitalizations which is an integral part of mental illness if not treated.

Secondly, injectable medications are necessary due to the issue of medication compliance that is inherent in mental illness. Medicare and Medicaid are not fully reimbursing for injectables, which has decreased access for the mentally ill patient. Public mental health centers are expected to absorb what Medi/Medi does not cover. This is not possible when public mental health centers operate with monies brought in from billing third party payers, not from general fund dollars.

Thank you for considering this concern as my ability to effectively care for my mother will be directly impacted by your decision.

Sincerely,
Sharon Killian

Submitter : **Ms. Denise Parkinson** **Date: 04/15/2005**

Organization : **Ms. Denise Parkinson**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Social Security Act ?1847B(a)(1)(A)(ii) states that each physician may select between the buy-and-bill model and the CAP model on an annual basis. Further, ?1847B(a)(1)(A)(iii) requires that each physician selecting the CAP option be given the opportunity to pick the CAP vendor of his or her choice. CMS?s apparent decision to make the choice between the buy-and-bill model and the CAP model a group practice decision rather than a physician-specific decision is contrary to the plain language of the statute. It is also inconsistent with Congress? stated intent that the choice of CAP should, as stated in the Conference Report, ?be completely voluntary on behalf of the physician.?

CMS has justified its decision to make the choice between buy-and-bill and CAP a group practice choice by saying that Social Security Act ?1847B(a)(5)(A) ?requires that we coordinate the physician?s election to participate in the CAP with the Medicare Participating Physician Process described in section 1842(h) of the Act.? That is not quite right. What ?1847B(a)(5)(A)(ii) actually requires is that ?[t]he selection of a [CAP] contractor . . . shall be coordinated with agreements entered into under section 1842(h).?

Instead of reading the statutory requirement to ?coordinate? the CAP vendor selection process with the Medicare Participating Physician Process simply as a directive to minimize paperwork by aligning the two selection processes in time and utilizing the same form for both, CMS has taken a very different tack. In so doing, it has converted the CAP selection process into a group practice decision and effectively eliminated the option of individual physician decision-making about CAP required by the statute and intended by Congress.

In some instances, physicians in group practices will be unable to come to agreement about the choice between the buy-and-bill model and the CAP model. Some physicians feel strongly about the risks to product integrity under CAP because of problems with counterfeit drugs experienced under commercial insurer MVI programs. Others are concerned about the potential impact on beneficiary access if CAP vendors are permitted to ?cut off? patients who fail to make timely coinsurance payments. Still others simply do not see how they can afford the increased administrative burden and increased drug-handling costs expected under CAP.

These types of concerns will be difficult to resolve and could result in situations where the CAP question causes practices to dissolve.

CMS has offered an unsatisfactory ?solution? to address the statutory requirement for individual physician choice: if the ?physician in the group practice also has a solo practice, he or she may make a different determination to participate or not to participate in the CAP when using his or her individual PIN.? In fact, this seems to invite groups that cannot agree on the CAP issue to break apart to preserve each camp?s ability to qualify as a group practice under the Stark Law. Although the provision of ?incident to? drugs furnished by a CAP vendor presumably will not trigger the Stark Law since a practice will have no financial stake in the outpatient prescription drugs, many group practices rely on the in-office ancillary service exception for purposes beyond drug treatment and would have legitimate concerns about the implications of a partial break-away of group members under the ?substantially all test? used to define group practices.

I recognize that CMS?s claims processing systems are set up based on group numbers and that carriers may need to implement system changes to deal with individual choice. And yet, I also recognize that the statute, the Conference Report, and even statements made by the CMS Administrator all share one crucial theme: participation in CAP will be a physician?s completely voluntary choice. Denying the right of individual choice simply to avoid system upgrades is unfounded and unacceptable.

Submitter : Dr. JOSE ACOSTAMADIEDO **Date:** 04/15/2005

Organization : VIRGINIA ONCOLOGY ASSOCIATES

Category : Physician

Issue Areas/Comments

1-15

Claims Processing Overview

I am concerned that the proposed rule?s delivery standards could pose a significant risk of increased financial and clinical costs to cancer patients. Today, cancer care practices routinely maintain a drug inventory to meet their patients? treatment needs. This has enabled practices to accommodate changes in patients? treatment plans without requiring the patient to return for therapy on another day. Under CAP, however, this level of service could be difficult if not impossible to maintain.

If chemotherapy sessions must be rescheduled to wait for the delivery of the drug(s) that patients need, they will face additional coinsurance obligations for the repeat physician services. In addition, patients will face other financial burdens in the form of higher transportation costs and additional missed time from work. This situation may also mean missed work time and reduced productivity for family members and other caregivers who must bring beneficiaries to the rescheduled treatment sessions.

I recognize that Social Security Act 1847B(b)(5) and the proposed rule permit physicians to receive replacement product from their CAP vendors for drugs taken from the physician?s inventory. Even if CAP physicians had a sufficient inventory to draw from, this option appears too narrowly tailored to save most patients from having to undertake a return trip and bear the cost of an additional coinsurance payment. Specifically, the use of the replacement program is limited to situations where the physician builds a record to demonstrate all of the following to the local carrier: (1) the drugs were required immediately, (2) the physician could not have anticipated the patient?s need for the drugs, (3) the CAP vendor could not deliver the drugs in a timely manner, and (4) the drugs were administered in an emergency situation.

There are a few glaring problems with the inventory replacement option. First, neither the statute nor the proposed rule defines ?emergency.? Moreover, neither the proposed rule nor the preamble discussion explains what a physician would have to show to justify immediate need or how the local carrier will assess whether the physician could have anticipated the patient?s drug needs sufficiently far in advance to permit delivery via the CAP vendor. Aside from the risk that the claim for replacement drug will be denied by the local carrier, the administrative burden of building this record may discourage many physicians from using the inventory replacement option. The inventory replacement option also raises the question about whether commercial insurers are being asked to subsidize a portion of the drug costs for Medicare beneficiaries in CAP, since Medicare would not be paying a physician for the ordering, financing, inventorying and handling costs associated with drugs borrowed from the practice?s inventory.

I are even more concerned about what this option could mean for patients, since it is not at all clear that oncology practices will be able to maintain full inventories after the implementation of CAP. Depending on their patient bases, the range of drugs that some practices would need for Medicare beneficiaries may not be the same as the drug inventory that the practice would stock for commercial patients. Moreover, if CAP encourages the proliferation of mandatory vendor imposition (MVI) programs among commercial carriers, it is likely that some practices may stop maintaining drug inventories altogether.

In sum, patients may be forced to pay both a financial and clinical price for treatment disruptions due to CAP, potentially exposing them to medical complications and increased emergency hospitalizations in addition to repeat visits and higher cost-sharing obligations.

Bidding Entity Qualifications

CMS is justifiably concerned about the need to ensure that CAP vendors are qualified to provide the services called for under Social Security Act ?1847B. I disagree, however, with two of the approaches that CMS has proposed for qualifying potential candidates.

CAP vendors must be licensed as a pharmacy in each state in their assigned service area. Although they may need to be licensed as a wholesaler as well, that credential alone is not sufficient because wholesalers are not permitted to ship patient-specific drug orders dispensed pursuant to a prescription. By focusing so extensively on distribution experience and the wholesaler credential, CMS is emphasizing the commodity aspect of the services that CAP vendors must provide, not the high-value aspects of those services.

Instead, CMS should focus on the dispensing aspects of a CAP vendor?s duties and pharmacy credentials. Just as important, CMS should place great emphasis on vendors? competence in patient-centric drug management services, in billing, claims processing, coordination of benefits and collections, and in their responsiveness to local market needs. Licensed pharmacies are more likely to have experience dealing with patient and physician complaints and are more likely to have, and be used to operating under, a code of conduct and a robust compliance program like that envisioned under 42 CFR ?414.914(c). It is these credentials that seem more relevant than CMS?s current focus on distribution capabilities.

I also disagree with the proposal to require all acceptable applicants to have 3 years of experience in ?the business of furnishing Part B injectable drugs.? Years of experience as a distributor are a poor proxy for the skill sets and capacity measures that will characterize efficient and effective CAP vendors. Moreover, the 3-year requirement will restrict competition and prevent new and higher quality entities from entering the market. A better approach would be to require that a bidder hold current pharmacy and wholesaler licenses in each state in the service area for which it is bidding and be enrolled as a Medicare supplier. CMS should then evaluate each applicant?s financial performance and solvency against pre-established criteria to identify organizations that are sufficiently capitalized to take on the challenge.

Similarly, CMS should collect information on personnel statistics, warehouse and dispensing capacities, distribution center locations, inventory sourcing relationships and the like and compare that information to pre-established criteria designed to ensure that the applicant has the wherewithal to handle the dispensing load CAP vendors can expected to face. It will be particularly important for vendors to have a broad geographic presence, either directly or through subcontract arrangements, with a wide network of pharmacies. Otherwise the vendor will be unable to make routine and emergency deliveries in time frames that meet patient

needs.

CMS also should gather data about each applicant?s experience in critical functions such as pharmacy services management, billing and collection, and compliance to evaluate the applicant?s ability to provide the level of service and quality necessary to support physicians who furnish Part B drugs in their offices and the Medicare beneficiaries who depend on them for care. As part of this process, CMS should consider checking references to assess how satisfied customers of a size commensurate with that of most oncology practices have been with past service.

In each of these areas, the bidder?s qualifications can be assessed not merely on the basis of their experience in the commodity service of distribution but in crucial service functions that will determine the difference between vendors who can safely and reliably serve CAP physicians needs, and those that cannot.

GENERAL

GENERAL

Issue Identifier: Overview of CAP

In its implementation of the Medicare Modernization Act of 2003 (MMA), the Centers for Medicare and Medicaid Services (CMS) has sought to more adequately cover the labor, supply, pharmacy, and other costs incurred in the administration of cancer-fighting drugs. Among the steps taken is the adoption of G codes to cover drug administration services and the creation of a demonstration project for 2005 that provided additional reimbursement.

As a result, 2005 Medicare reimbursement for cancer care services is considerably higher than pre-MMA rates. However, total reimbursement will drop dramatically on January 1, 2006, when the demonstration project is scheduled to end and the drug administration transitional factor will be zeroed out.

It has been calculated that the impact of these changes will translate into a $940 underpayment for drug administration services per Medicare beneficiary. Put another way, 2006 Medicare reimbursement for patient care services will cover only an estimated 50.09% of drug administration costs.

This problem is a key factor in the implementation of the Competitive Acquisition Program (CAP) in 2006. Under CAP, middlemen vendors will furnish drugs to physicians who choose to give up the traditional buy-and-bill model and select the CAP model instead. The vendors will be responsible for billing Medicare for the drugs, and the physicians will receive reimbursement only for drug administration services.

CMS expects CAP to appeal to those physicians ?who do not want to be in the drug procurement and drug coinsurance collection business? [70 Fed. Reg. 10750]. Indeed, statements made by CMS and CAP?s Congressional authors all reinforce the notion that CAP is intended to be an option that physicians may choose to adopt in place of the current buy-and-bill model. According to the MMA Conference Report produced by Congress, ?Conferees intend this choice to be completely voluntary on behalf of the physicians? [H. R. Conf. Rep. No. 108-391, 108th Cong., 1st Sess. 593 (2003)].

And yet, it is possible that neither CMS nor Congress has recognized that the viability of these two choices turns on the adequacy of reimbursement for drug administration services. Unless changes are made, many oncologists will face a loss under the buy-and-bill model, a loss that will be even greater should they opt to participate in CAP. This is because the only reimbursement they will receive under CAP is payment for drug administration services ? which will fall well below the cost of providing drug administration services.

In light of the reimbursement shortfall that looms on January 1, 2006, many cancer care specialists will face a very different choice than the one that Congress intended: continue to offer cancer care services to seniors (under buy-and-bill or CAP) and incur a significant net loss?or discontinue offering chemotherapy services to Medicare beneficiaries altogether. Sadly, both approaches threaten the community cancer care services on which millions of Americans now depend.

Congress has clearly stated its intent that patient access to community cancer care must be preserved because it is the source of convenient, cost-effective care for more than 4-out-of-5 American cancer patients. If CMS intends to abide by this intent, it must take additional steps to align Medicare reimbursement with the cost of drug administration services.

Because the level of needed fee schedule restructuring is significant, CMS may be unable to solve this pending crisis before the 2006 Physician Fee Schedule must be published. As a result, I urge CMS to extend the quality demonstration while it works to match drug administration cost and payments. Otherwise, both the CAP and the ASP models will be doomed to failure and many Medicare cancer patients likely will be forced back to hospitals for chemotherapy.

Submitter : Dr. jonathan britell **Date:** 04/16/2005

Organization : valley internal medicine

Category : Physician

Issue Areas/Comments

1-15

Competitive Acquisitions Areas

Issue Identifier: Competitive Acquisition Areas

A key issue relating to Competitive Acquisition Areas is the requirement that CAP vendors have arrangements in place sufficient to permit shipment ?at least 5 days each week for competitively biddable drugs and biologicals . . . and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract.? (See also 42 CFR 141.914(f)(2)). We appreciate CMS?s request for comments both on ?how to define timely delivery for routine and emergency drug shipments? and on the ?feasibility of providing same day deliveries for orders received for emergency situations? (70 Fed. Reg. 10745,10760 (March 4, 2005)).

I believe that the proposed timelines for routine and emergency delivery are inadequate and that vendors must be required to make routine deliveries anywhere in their service area within 24-hours of a practice?s submission of a new prescription 7 days a week. I base this recommendation on three principle considerations. First, it is not unusual for oncology practices to operate 6 and 7 days a week to meet their patients? needs. Second, it is estimated that approximately one-third of treatment plans must be modified on the day of treatment due to changes in a patient?s health status. Third, the unavailability of drugs needed on the day of treatment would pose a significant burden on patients who would have to return another day for treatment. This burden can be particularly severe in rural areas were patients may have to travel long distances to receive cancer care.

CMS has the authority to require that CAP vendors be able to delivery drugs within 24 hours 7 days a week under the statutory language in Social Security Act ?1847B(b)(2)(A)(i)(II). That provision imposes two standards on CAP vendors: the ability to make timely deliveries and the ability to ship at least 5 days each week. I believe that CMS should use its authority to define ?timely delivery? as a 24-hour turn around and 7-day-a-week delivery services. I fear that anything less could jeopardize the ability of cancer care specialists to meet their patients? clinical needs.

I believe CMS should not rely on an expectation that oncologists who choose CAP will continue to maintain an adequate inventory of drugs that can be used to treat Medicare patients in emergencies under the inventory replacement provisions of the CAP rule. CAP is expected to spur growth in commercial payers? mandatory vendor imposition (MVI) programs. As a result, some physicians who elect CAP and continue offering in-office drug administration services may cease to maintain any on-site drug inventories. Even those practices that maintain inventories may limit them for a variety of reasons, including differences in the clinical needs of their Medicare and non-Medicare patient bases.

Finally, I note that neither the changes to 42 CFR 414.902 set forth in the proposed rule nor the text of the existing regulation define the term ?emergency.? It is essential for the definition of emergency to be clearly set forth in the final rule and not left to the discretion of each CAP vendor or to the discretion of local carriers tasked with adjudicating practices? claims for drug administration services. Moreover, the definition should turn on the treating physician?s clinical judgment that patient health would suffer from delay in treatment, not on the CAP vendor?s or the local carrier?s remote assessment of the situation.

In closing, I respectfully urge CMS to implement the ?timely delivery? requirement established by MMA as requiring CAP vendors to be able to deliver ordered drugs within 24 hours, 7 days a week.

Overview of the CAP

Issue Identifier: Overview of CAP

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to participate in CAP. This is because the only reimbursement they will receive under CAP is payment for drug administration services ? which will fall well below the cost of providing drug administration services.

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Dispute Resolution

Issue Identifier: Claims Processing Overview
Dispute Resolution

According to the preamble to the Proposed Rule, CMS believes that CAP will not significantly increase the administrative burden on physicians. As a result, CMS has concluded that the payment for clerical and inventory management services that is bundled into the drug administration codes should be adequate to cover the practice expenses which physicians will occur under CAP. This is unrealistic for a number of reasons, including the following:

First, CAP practices will have to implement and operate a second, separate ordering process for CAP drugs to transmit patient-specific drug orders that include demographic and clinical information. The ordering system under the buy-and-bill model is much simpler because aggregate orders based on practice usage are placed with wholesalers. Buy-and-bill ordering does not involve the review of individual patient charts nor does it require input of substantial amounts of data for each vial of drug requested from the wholesaler.

Second, CAP will increase the demands on oncology practices for pharmacy management services. Changes in individual treatment plans will have to be closely monitored so that new prescriptions can be sent to the vendor in timely fashion. The job of ensuring that drugs are given to the right patient and that patient-specific drug supplies provided in multi-dose vials have not expired or passed stability deadlines before the entire vial is used will be more complicated because the time that any particular multi-dose vial must be maintained and monitored will increase. The increases in complexity of required pharmacy management services will also increase the risk of medication errors.

A study of oncology pharmacy costs by the University of Utah on behalf of the Global Access Project suggests that the average cost of these services per dose of chemotherapy preparation is already $36.03. Since the current level of pharmacy services costs is not captured in the practice expense component of payments for drug administration services, the new costs imposed by CAP will be both additive and uncompensated.

Third, CAP will likely increase hazardous waste disposal costs substantially due to complications regarding the redirection, in the physician?s office, of unused drug dispensed for one patient to another patient. Waste handling costs will also be higher under CAP due to the increased likelihood that a drug designated for a particular patient will pass its expiration or stability deadline before all of the vial can be finished. As a result, total waste quantities could quickly exceed levels allowable for routine disposal, thereby adding even greater costs.

Fourth, CAP physicians will face much higher claims administration costs. CAP requires Medicare claims for drug administration services to be filed within 14 days of the drug administration service. This represents an increased burden since the Proposed Rule acknowledges that only about 75% of claims currently are filed within this timeframe and since claims processing software will need to be upgraded. Further, CAP physicians will be unable to make a cost-benefit decision about the value of appealing a claim denial for drug administration services. Instead, physicians could be forced to appeal all denials in a process that requires all the evidence needed to support the appeal to be collected and submitted.

Given the management, inventory control, drug preparation, paperwork, integrity assurance, and other necessary new or enhanced functions that will face physicians selecting CAP, CMS should establish a new HCPCS code for pharmacy management services to compensate physicians. To address the hazardous waste disposal problem, CMS should also require each CAP vendor to subcontract with properly licensed and permitted hazardous waste haulers and disposers to pick up from physicians discarded drugs dispensed by the ve

Contract Requirements

Issue Identifiers: Contract Requirements

The World Health Organization estimates that 6% of all drugs distributed in the world are counterfeit and some observers believe it to be as high as 12%. Since most counterfeit drugs in the US enter the chain of commerce through the secondary market, I applaud Congress? decision to require CAP vendors to acquire all of their drugs directly from the manufacturer or from a wholesaler that buys direct.

Product integrity is about more than blocking the distribution of counterfeit goods, however. That is why I am concerned that the Proposed Rule?s provisions could jeopardize product integrity and violate state licensing laws.
I suspect that CMS may not have thought through licensing and product integrity issues because it seems to have concluded that CAP vendors should be licensed as wholesalers but not as pharmacies. Indeed, many provisions in the Proposed Rule and the entire discussion of product integrity in the preamble focuses on wholesale distributors.
I am convinced that CAP vendors must be licensed as pharmacies, however. The statute does not expressly define the class of trade of a CAP vendor and ?1847B(b)(4)(C) could suggest that Congress viewed CAP vendors as wholesalers. And yet, Social Security Act ?1847B(b)(6) seems to take a different position, stating that nothing in Social Security Act ?1847B ?shall be construed as waiving applicable State requirements relating to licensing of pharmacies.?

CAP vendors must be licensed as pharmacies because they will accept patient-specific written orders for prescription drugs from physicians, assign prescription numbers to those orders, interpret the orders, presumably making generic substitutions as appropriate and permissible under applicable State law, and then transfer dispensed drugs to the prescribing physician for administration to the patient. This patient-specific transfer amounts to ?dispensing? a drug under state pharmacy practice acts and because CAP vendors dispense, they are practicing pharmacy and must be licensed accordingly.
Since CAP vendors must operate as licensed pharmacies, some of the operational aspects of CAP seem unworkable or in need of retooling. For example, state pharmacies laws do not permit a pharmacist to assign different prescription numbers to successive fills of a single prescription. Rather, prescription refills are always dispensed under the prescription number assigned to the original written order. A new prescription number is assigned only when a new written order is received. These practices are inconsistent with the prescription numbering system described in the preamble to the Proposed Rule.

Another critical problem is posed by CMS?s proposal for dealing with CAP drugs that cannot be administered to the beneficiary for whom they were prescribed. Most state pharmacy laws prohibit the restocking of unused drugs after they have been dispensed. By establishing a process for the restocking and use of previously-dispensed drugs, however, the proposed rule appears to put the physician in the position of aiding and abetting the violation of these state pharmacy laws. In fact, none of the laws of which I am aware allow dispensed product to be redirected to another patient without going back to the dispensing pharmacy first.

Redirecting unused drugs dispensed by a CAP vendor from the intended recipient to another patient could expose physician practices to tort liability. Physicians participating in CAP will therefore need indemnification from CAP vendors when reuse decisions about drugs belonging to the vendor, not the physician, are made based on discussions with the CAP pharmacist. CMS should build requirements for appropriate indemnities into the final rule.

Claims Processing Overview

Issue Identifier: Claims Processing Overview

I am concerned that the proposed rule?s delivery standards could pose a significant risk of increased financial and clinical costs to cancer patients. Today, cancer care practices routinely maintain a drug inventory to meet their patients? treatment needs. This has enabled practices to accommodate changes in patients? treatment plans without requiring the patient to return for therapy on another day. Under CAP, however, this level of service could be difficult if not impossible to maintain.

If chemotherapy sessions must be rescheduled to wait for the delivery of the drug(s) that patients need, they will face additional coinsurance obligations for the repeat physician services. In addition, patients will face other financial burdens in the form of higher transportation costs and additional missed time from work. This situation may also mean missed work time and reduced productivity for family members and other caregivers who must bring beneficiaries to the rescheduled treatment sessions.

I recognize that Social Security Act 1847B(b)(5) and the proposed rule permit physicians to receive replacement product from their CAP vendors for drugs taken from the physician?s inventory. Even if CAP physicians had a sufficient inventory to draw from, this option appears too narrowly tailored to save most patients from having to undertake a return trip and bear the cost of an additional coinsurance payment. Specifically, the use of the replacement program is limited to situations where the physician builds a record to demonstrate all of the following to the local carrier: (1) the drugs were required immediately, (2) the physician could not have anticipated the patient?s need for the drugs, (3) the CAP vendor could not deliver the drugs in a timely manner, and (4) the drugs were administered in an emergency situation.

There are a few glaring problems with the inventory replacement option. First, neither the statute nor the proposed rule defines ?emergency.? Moreover, neither the proposed rule nor the preamble discussion explains what a physician would have to show to justify immediate need or how the local carrier will assess whether the physician could have anticipated the patient?s drug needs sufficiently far in advance to permit delivery via the CAP vendor. Aside from the risk that the claim for replacement drug will be denied by the local carrier, the administrative burden of building this record may discourage many physicians from using the inventory replacement option. The inventory replacement option also raises the question about whether commercial insurers are being asked to subsidize a portion of the drug costs for Medicare beneficiaries in CAP, since Medicare would not be paying a physician for the ordering, financing, inventorying and handling costs associated with drugs borrowed from the practice?s inventory.

I are even more concerned about what this option could mean for patients, since it is not at all clear that oncology practices will be able to maintain full inventories after the implementation of CAP. Depending on their patient bases, the range of drugs that some practices would need for Medicare beneficiaries may not be the same as the drug inventory that the practice would stock for commercial patients. Moreover, if CAP encourages the proliferation of mandatory vendor imposition (MVI) programs among commercial carriers, it is likely that some practices may stop maintaining drug inventories altogether.

In sum, patients may be forced to pay both a financial and clinical price for treatment disruptions due to CAP, potentially exposing them to medical complications and increased emergency hospitalizations in addition to repeat visits and higher cost-sharing obligations.

Categories of Drugs to be Included under the CAP

Issue Identifier: Categories of Drugs To Be Included Under the CAP

The design and implementation of a competitive acquisition program for Part B drugs is an enormous undertaking. It is also an undertaking that will move Medicare into largely uncharted waters. That fact alone argues for a cautious approach.

Although CMS has managed two competitive acquisition demonstration projects for certain types of durable medical equipment, prosthetics and supplies (DMEPOS) in limited geographic markets, it has never organized and run a competitive acquisition program on a national or even a regional scale. The Part B drug CAP differs significantly from the DMEPOS demonstrations because of complicated state licensing and regulatory schemes, the criticality of most of the products involved from a beneficiary perspective, the single-source nature of many of the drugs to be furnished, and the necessity for substantial changes in Medicare claims processing systems that go beyond anything required to implement the DMEPOS demonstrations.

With DME, there were numerous established suppliers operating in a largely unregulated state licensure environment. Because participation in the demonstration by

Medicare beneficiaries living in the test areas was mandatory, the bidders knew the size of the potential market. The bidders also ran established businesses and clearly understood the cost structures of those businesses. Unlike the situation with single-source drugs that are the standard of care for many cancer patients today, each product category subject to DMEPOS competitive bidding included numerous items under most HCPCS codes subject to the demonstration. Also unlike the situation that will face manufacturers of Part B drugs in 2006, the discounts extended to DMEPOS competitive bidders did not impact Medicare reimbursement for the manufacturer?s product in locations outside the demonstration area. In other words, with DMEPOS, CMS could count on an adequate supply of qualified bidders positioned to put forth bids consistent with required quality and service standards without sacrificing reasonable profitability and jeopardizing solvency. Furthermore, the product categories included in the DMEPOS demonstrations are not generally seen as carrying the same level concern about product integrity or medical errors as do Part B drugs. Therefore, if DMEPOS CAP vendors stinted on quality or service, the likely outcome for beneficiaries was not as potentially significant as if problems develop with the Part B drug CAP.

The GAO issued a final report to Congress assessing the DMEPOS demonstrations in September 2004. In that report, the GAO suggested that CMS consider conducting more competitive bidding demonstrations for items and services not in the original demonstrations prior to the beginning of the MMA-mandated implementation of CAP for DMEPOS.

This suggestion argues for taking a slow approach to the Part B drug CAP. In fact, it appears that CMS may already agree. In its final report on the DMEPOS CAP demonstration projects, CMS observed ?one of the benefits of conducting demonstrations projects is the ability to learn from the demonstration and apply the lessons if the demonstration is adopted on a wider scale.?

Instead of diving into a national CAP involving all Part B drugs used in ?incident to? services, CMS should begin with a regional or national test involving a limited set of drugs that are typically administered by a physician specialty that uses drugs less intensely than oncology. This would allow CMS to refine its application and vendor selection procedures and its quality and service requirements, correct glitches in CAP upgrades to its claims processing systems, work out handling issues stemming from state regulations, assess and adjust for changes in practice expenses attributable to CAP, and complete the work needed to better match the reimbursement rates for drug administration services to actual cos

Contracting Process-Quality and Product Integrity Aspects

Issue Identifier: Contracting Process ? Quality and Product Integrity Aspects

In an effort to ensure the stability of CAP, MMA directs CMS to require CAP vendors to meet standards for quality, service, financial performance and solvency that include appropriate procedures for the resolution of physician complaints and grievances. Unfortunately, the statute offers few specifics regarding these standards, and the proposed rule does not define all of the standards to which the vendors will be held. As it has done in the DMEPOS Supplier manuals, CMS should issue CAP guidance that defines measurable quality, service, financial performance and solvency standards.

With respect to Quality and Service Standards, I believe CMS should focus on standards related to shipment errors (e.g., wrong drug or dose; wrong quantity; damaged packaging; inadequate refrigeration; counterfeit product, etc.) and timely deliveries, both for routine and emergency deliveries. I also believe that the required physician call centers need to operate a minimum of 12 hours per day and that call management standards should tightly limit ring time, hold time, and dropped calls.

When it comes to Clinical Standards, I applaud CMS?s decision to make the local carriers the arbiters of coverage and medical necessity decisions. In oncology, drugs can be extremely expensive, compendium-supported off-label usage is statutorily mandated, and off-label usage supported by peer-reviewed literature is also commonly reimbursed. As a result, CMS is right not to place decisions about coverage and medical necessity in the hands of vendors.

I am concerned, however, about the administrative burden on physician practices that will result from the CAP Election Agreement?s requirement that physicians appeal all denied drug administration claims. The proposed rule provides no guidance on how many levels of appeal the physician must pursue, but the draft Election Agreement requires appeal through the reconsideration level. For clarity, we urge CMS to include this limitation in the final rule. The burden of appealing every denied drug administration claim is heightened by the pending changes in the claims appeal process that become effective on May 1, 2005. Given the magnitude of those changes, CMS should require the CAP vendor to request clinical literature from drug manufacturers needed to support appeals of drug administration denials.

I am also concerned that the proposed rule ignores the significant risk that physicians could face litigation over adverse drug events due to drugs provided by a CAP vendor. I strongly urge CMS to require CAP vendors to indemnify physicians for all costs, including reasonable attorney?s fees, associated with the defense of all such actions where the physician is ultimately exonerated. The indemnification may be prorated if the physician is found to be partly liable and there is a rational basis for apportioning costs between the CAP vendor and the physician.

With respect to Financial and Solvency Standards, I commend CMS?s decision to assess CAP bidders using Federal Acquisition Regulation (FAR) criteria, adopt FAR business integrity and conflicts of interest standards, and review third-party information on the structure and effectiveness of CAP bidders? internal control systems. The proposed rule does not specify how CMS will ensure ongoing compliance with vendor performance requirements, however, so CMS should issue a detailed guidance document, require CAP vendors to report key performance statistics quarterly, and consider imposing contractually defined financial penalties for sub-par performance in addition to the imposition of False Claims Act liability that vendors face.

Cap Bidding Process-Evaluation and Selection

Issue Identifier: CAP Bidding Process ? Evaluation and Selection

CMS intends to contract only with qualified CAP bidders that submit composite bids with a weighted average price per HCPCS unit that is no greater than 106% of the weighted ASP for the drugs in the category. US Oncology has consistently taken the position that reimbursement at 106% of ASP is inadequate to cover physicians? costs for chemotherapy drugs and for pharmacy management services and other associated expenses, including bad debt, that are currently not considered in the practice expense component of the drug administration G codes.

Just as I believe this level of reimbursement is inadequate for physicians under the buy-and-bill model, so too do I view reimbursement at 106% of ASP to be inadequate under the CAP model. Competition will not cause manufacturers of most single-source drugs to discount their products to CAP vendors or to any other

class of buyer that must be considered when Best Price is calculated. And, like physician practices nationwide, bad debt will pose a major financial challenge to CAP vendors.

In addition, CAP vendors will incur significant middleman costs, including administrative, dispensing, shipping, product disposal, and bad debt costs. These costs are borne by physicians practices everyday, but CAP vendors will likely face even greater difficulty collecting due to the time delay between the dates of treatment and payment, as well as their lack of a direct relationship with patients. Beneficiaries who are already contending with deductibles and coinsurance payments not covered by secondary insurance, travel expenses, custodial care expenses, costs associated with changed dietary needs, etc., may place a relatively low priority on paying their CAP vendors.

Just as the absence of personal relationships between beneficiaries and CAP vendors is likely to exacerbate the vendors? bad debt collection problems, I fear it will also exacerbate some vendors? use of overly aggressive collection efforts, including decisions to stop providing drugs for patients who are too far in arrears. The Practicing Physicians Advisory Council has also raised this concern and proposed that CMS address it in the final CAP rule by mandating that vendors advance credit to patients unable to afford their coinsurance payments. CMS should go a step further and ask that the vendors also be required to have in place procedures for assessing indigence and waiving coinsurance when a non-Medicaid-eligible beneficiary?s income, assets, and medical expenses meet certain pre-established criteria. Ideally, these procedures should incorporate the assistance of social workers trained to explore all payment options and assistance programs available to the individual.

Unlike the situation with physicians where reimbursement for Part B drugs supplied under the buy-and-bill model is set by statute at 106% of ASP, CMS may have the discretionary authority under Social Security Act ?1847B to permit payments to CAP vendors at any level necessary to compensate them fairly and appropriately for their services. It appears that Congress only expected competition under the CAP model to save money on multi-source drug products, not single-source drugs and biologicals.

Pre-defining an unrealistically low reimbursement cap could under-capitalize vendors, resulting in too few qualified bidders, the provision of improper services, and patient harm. Therefore, CMS should either abandon the notion that CAP will save money in the aggregate for Medicare Part B or phase in the program slowly by starting with a small group of drugs or with a specialty that does not use ?incident to? drugs intensively to test the impact of an potentially under-reimbursed CAP model on beneficiary access to care and on the robustness and financial viability of the CAP vendor market.

In either case, one conclusion should be recognized: just as 106% of ASP is too low in the buy-an

Bidding Entity Qualifications

Issue Identifier: Bidding Entity Qualifications

CMS is justifiably concerned about the need to ensure that CAP vendors are qualified to provide the services called for under Social Security Act ?1847B. I disagree, however, with two of the approaches that CMS has proposed for qualifying potential candidates.

CAP vendors must be licensed as a pharmacy in each state in their assigned service area. Although they may need to be licensed as a wholesaler as well, that credential alone is not sufficient because wholesalers are not permitted to ship patient-specific drug orders dispensed pursuant to a prescription. By focusing so extensively on distribution experience and the wholesaler credential, CMS is emphasizing the commodity aspect of the services that CAP vendors must provide, not the high-value aspects of those services.

Instead, CMS should focus on the dispensing aspects of a CAP vendor?s duties and pharmacy credentials. Just as important, CMS should place great emphasis on vendors? competence in patient-centric drug management services, in billing, claims processing, coordination of benefits and collections, and in their responsiveness to local market needs. Licensed pharmacies are more likely to have experience dealing with patient and physician complaints and are more likely to have, and be used to operating under, a code of conduct and a robust compliance program like that envisioned under 42 CFR ?414.914(c). It is these credentials that seem more relevant than CMS?s current focus on distribution capabilities.

I also disagree with the proposal to require all acceptable applicants to have 3 years of experience in ?the business of furnishing Part B injectable drugs.? Years of experience as a distributor are a poor proxy for the skill sets and capacity measures that will characterize efficient and effective CAP vendors. Moreover, the 3-year requirement will restrict competition and prevent new and higher quality entities from entering the market. A better approach would be to require that a bidder hold current pharmacy and wholesaler licenses in each state in the service area for which it is bidding and be enrolled as a Medicare supplier. CMS should then evaluate each applicant?s financial performance and solvency against pre-established criteria to identify organizations that are sufficiently capitalized to take on the challenge.

Similarly, CMS should collect information on personnel statistics, warehouse and dispensing capacities, distribution center locations, inventory sourcing relationships and the like and compare that information to pre-established criteria designed to ensure that the applicant has the wherewithal to handle the dispensing load CAP vendors can expected to face. It will be particularly important for vendors to have a broad geographic presence, either directly or through subcontract arrangements, with a wide network of pharmacies. Otherwise the vendor will be unable to make routine and emergency deliveries in time frames that meet patient needs.

CMS also should gather data about each applicant?s experience in critical functions such as pharmacy services management, billing and collection, and compliance to evaluate the applicant?s ability to provide the level of service and quality necessary to support physicians who furnish Part B drugs in their offices and the Medicare beneficiaries who depend on them for care. As part of this process, CMS should consider checking references to assess how satisfied customers of a size commensurate with that of most oncology practices have been with past service.

In each of these areas, the bidder?s qualifications can be assessed not merely on the basis of their experience in the commodity service of distribution but in crucial service functions that will determine the difference between vendors who can safely and reliably serve CAP physicians needs, and those that cannot.

GENERAL

GENERAL

Currently, physicians have barely had enough time to evaluate their experience with the ASP+6% buy and bid system. Carriers have only now corrected some of the early clitches in the system that prevented processing of clean bills submitted to them.The early election date of November allows us only 6 more months of experience to see it system actually works. The one escape that practices have is to opt out effectively by sending patients to hospital outpatient infusion units that cost more to the system and to the patients and that require extra travel and extra time to complete therapy that is provided more efficiently in the physician's office. As a physician in a 4 person group, I have grave reservations about the CAP program. As President of the Washington State Medical Oncology Society, I hear my sentiments echoed on a daily basis from our membership.

I fear that the initiation of the Part D benefit is going to cause significant stress on patients and on physician's offices trying to help patients negociate this new system Our experience with the Demonstration Project Lottery for chemotherapy, anti breast cancer drugs, thalidomide, tarceva, irressa and gleevec has shown us how upset and confused patients have been and will be by this new system. Tackling the CAP process on top of the confusion expected to be engendered by Part D will be an onerous task. I would urge the delay of the roll out of CAP with regard to the oncology drugs until 2007 to allow medical oncologists to come to grips with all the changes we are experiencing.

Thank you,

Jonathan C. Britell MD
President,
Washington State Medical Oncology Society and

Valley Internal Medicine
Renton Washington

Submitter : **Mrs. Loretta Goodson** **Date: 04/17/2005**

Organization : **Northeast Georgia Cancer Care, LLC**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Our practice is extremely concerned and find it to be very difficult for the CAP Program to work in our clinics. We are a practice with four Medical Oncologist serving sixteen different counties in rural Georgia. We have one main location and seven satellite locations which are leased. Our physicians have been very dedicated to serving these rural locations but are finding it more difficult as CMS implements programs that add to our cost. Below are the following concerns our practice identifies with CAP:

1. Our patients would be required to travel 60-100 miles to receive treatment if the physician needed to change treatment protocol.
2. It would be impossible to maintain two different inventory systems in these satellite locations. These locations do not have access to cancer care in their local hospitals!
3. What happens to the Medicare patient who can't pay the 20% to the choosen vendor???? Patients will choose not to receive treatment.
4. The administrative burden will drive the cost up for community oncology practices.
5. Community Oncologist have not been involved or survey to see if this program would be successful!

I want to thank you for allowing community oncology the opportunity to comment and encourage CMS to seek assistant from community oncology.

Loretta Goodson

Submitter : Griselle Piferrer **Date:** 04/18/2005

Organization : Ocala Oncology Center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I feel that after reviewing the full program this will impact negatively both the vendors and the practice. This proposal is an administrative nightmare. Ultimately the patient will end up suffering the consequences. Just like all other changes, cancer care is a stake here.

Submitter : **Mr. George Braunstein** **Date: 04/18/2005**

Organization : **Chesterfield Community Services Board**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

Chesterfield Community Services Board in Virginia would strongly urge CMS to include categories of psychiatric medications in its CAP project. This would be a great benefit to consumers with serious mental illness and their treating physician. Currently the process is convoluted and costly. Allowing psychiatric medications, including long-acting injectables, to be part of CAP will streamline the process, reduce administrative and billing overhead and promote longevity of use by the consumer. This will greatly reduce episodes that require the most expensive care-hospitalization, and most importantly, improve access to care for consumers.

Should you need further information, please contact me at braunsteing@chesterfield.gov

Thank you
George Braunstein
Executive Director

Submitter : **Dr. Thomas Gazda** **Date: 04/18/2005**

Organization : **Banner Behavioral Health**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir/Madam,

I work as an inpatient psychiatrist at Banner Behavioral Health, Scottsdale Arizona and am involved in clinical neurosciences research. Many of the incredible advances in long term medications for severely incapacitating illnesses such as schizophrenia and bipolar disorder are not available to patients in need because of lack of coverage. Long acting injectable meds such as risperdal consta have shown remarkable potential benefit to this patient population that in general suffer from stigmatization and prejudice when it comes to coverage. I believe the mentally ill as a group represent the major civil rights challenge of the new millennia.

I implore you to ensure that long acting injectables are made available to this disadvantaged group of patients.

Yours sincerely,

Thomas Gazda MD

Submitter : Jerry Mayo **Date: 04/19/2005**

Organization : Pine Belt Mental Healthcare Resources

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

I am writing to encourage the inclusion of injectable antipsychotics in the competive acquisition program. These medications are very expensive.The present system of acquisition and billing is cumbersome and discourages utilization of these medications. While there are very few of these medications presently on the market, I would expect others to be available in the near future. Addressing this issue at this time will ensure timely access to medications that may improve the lives of our consumers in the future. Thank you for your consideration of this request. Jerry Mayo

Submitter : Dr. Randy Kerswill **Date:** 04/19/2005

Organization : Winnebago Mental Health Institute

Category : Physician

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

Patients with chronic mental illness offer unique challenges as far as treatment. Lack of insight, substance abuse, compliance issues and access to care issues all contribute to poorer outcomes. It is extremely important to insure improved access to care and I believe the CMS Competitive Acquisition program is an important step in that direction. I am requesting that CMS include all mental health therapies in phase 1 (1/1/06) of the CAP. This will improve consumer access to care for people with chronic mental illnesses.

Submitter : Dr. Andrew Sher **Date:** 04/19/2005

Organization : Dr. Andrew Sher

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

A provider should have the ability to elect into the system more than once per year

There needs to be a higher re-imbursement to cover expenses associated with the overhead to be a participant within this system. These drugs have great potential benefits, but they also have risks (as do all treatments). The re-imbursement to discuss these risks and continue to administer these meds needs to reflect these risks.

Submitter : Mr. John Adams **Date:** 04/19/2005

Organization : Viewmont Urology Clinic, PA

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am the business manager for a 5 Urologist Practice. The CAP program as it exists is very cumbersome from an administrative standpoint. We would have to hire a full time person to handle the administrative nightmare. This eliminates the main reason to enter the CAP program-"to remove the potential of financial losses from the ASP + 6% methodology of drug reimbursement". We purchase drugs in bulk currently. We purchase many drugs in increments above 20. It would be very inefficient to have to do a prescription for each drug. We would have to establish 2 inventories-Medicare and nonmedicare. We also have patients who have ongoing treatments that do not show because of any one of a number of reasons. We would need to do something with those prescriptions. Please simplify the CAP program and reduce the administrative burden!!!!!!

Submitter :

Date: 04/19/2005

Organization : **National Mental Health Association**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-126-Attach-1.DOC

CMS-1325-P-126-Attach-2.DOC

National Mental Health Association

Headquarters: 2001 North Beauregard Street, 12th Floor, Alexandria, VA 22311-1732• Phone (703) 684-7722 • Fax (703) 684-5968
Government Affairs Office: 413 East Capitol St, SE, Washington, DC 20003-9997 • Fax (202) 675-8389 • www.nmha.org
Cynthia Wainscott, **Chair of the Board** • Michael M. Faenza, **President and CEO**

April 19, 2005

The Honorable Mark McClellan
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. McClellan:

On behalf of the National Mental Health Association, I am writing to you regarding the Center for Medicare and Medicaid Services' (CMS') proposed regulation [CMS-1325-P] to establish a Competitive Acquisition Program (CAP) for medications covered by Medicare Part B. We are particularly interested in the impact this regulation will have on access to mental health medications.

We continue to be dismayed by the fact that Medicare imposes more restrictive limits and much higher out-of-pocket costs for mental health care than for the care of other illnesses. Of particular concern is the 50 percent co-payment that applies to Part B coverage of outpatient mental health services, instead of the usual 20 percent required for other outpatient care. This unequal and unfair barrier to treatment for individuals with mental illness under the Medicare program is inconsistent with growing and widespread recognition that mental illnesses are real and can be severely debilitating without treatment. The 50 percent co-pay represents a tax on mental health care that is grounded in stigma.

As you know, mental illness affects a very large segment of the Medicare population, but with the discriminatory restrictions and added costs imposed on mental health treatment under this program, few receive the treatment they need. Some 20 percent of older Americans and 40 percent of those on Medicare because of a disability, face mental illness. Yet, all too often they struggle with this disease alone, without treatment and support. In fact, research indicates that two-thirds of those who need mental health care do not receive it. This lack of care has tragic consequences as illustrated by the fact that older adults have the highest rate of suicide in the country, accounting for 20 percent of suicide deaths.

This high co-payment requirement for mental health services has also impeded access to certain types of mental health medications covered by Medicare Part B – such as injectible anti-psychotic medication. Overly complex and confusing reimbursement policies for this type of medication have caused physicians to discontinue use of it for financial reasons instead of therapeutic reasons. The heightened risk of non-reimbursement associated with this type of medication also discourages physicians from even offering it to consumers who may benefit from it.

As you know, mental health disorders require highly individualized treatment. Mental illnesses vary greatly in their symptoms and effects on consumers. In prescribing mental health medications, physicians must take into account myriad factors including past treatment history, likely responses to side effects, other medications currently being taken, any co-morbidities (which are common among individuals with mental illness), and overdose safety, given the heightened risk of suicide. As a result, in order to receive effective treatment, consumers need access to the full array of treatment options.

Thus, we encourage you to include mental health medications in the list of medications covered by the CAP program as of January 1, 2006. The inclusion of these medications in the CAP program would conform with the recommendation by President Bush's New Freedom Commission on Mental Health that "[a]ny effort to strengthen or improve Medicare and Medicaid programs should offer beneficiaries options to effectively use the most up-to-date treatments and services."[1]

Thank you for your consideration of our views. If you have any questions, please contact Kirsten Beronio, Senior Director of Government Affairs at 202-675-8413.

Sincerely,

Michael M. Faenza, MSSW
President and CEO

[1] New Freedom Commission on Mental Health, Final Report, *Achieving the Promise: Transforming Mental Health Care in America,* p. 26 (July 2003).

Submitter : **Mrs. Nita Folden** **Date: 04/19/2005**

Organization : **Mountainside mental health**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

Mountainside Mental Health
10209 Bridgeport Way SW D-10
Lakewood, Washington, 98499
Phone: 253-460-9414

April 13, 2005

CMS
Department of Health & Human Services
Attention: CMS-1325-P
PO Box 8010
Baltimore, MD 21244-8010
Via Email: www.cms.hhs.gov/regulations/ecomments

Dear Sir/Madam,

I am writing to you to express my concerns about the possibility that injectable antipsychotics will not be covered under the proposed Competitive Acquisition Program under the Medicare Modernization Act. As I will explain, this would have devastating consequences for many of my Medicare patients.

Mountainside is a small but growing practice that takes care of the mental health needs of many patients with severe mental illness, including schizophrenia. Last year we saw a new medication hit the market, namely Risperdal Consta. It was different from what was already out there in several ways, the most pertinent of which was reimbursement. Instead of having a local pharmacy process all claims as is usually the case with psychiatric medications, we were told that Medicare required that we buy it first and bill them later. We did this, even though it put us in a difficult financial situation and strained the limited time that my administration staff had. Unfortunately, everything didn?t work out. We wound up losing a considerable amount of money because of the difficult system.

As a small business owner I cannot and will not accept further financial risk associated with billing Medicare. As I see it, it is not our role to bill Medicare, that is the role of pharmacies. Should the Competitive Acquisition Program not include injectable antipsychotics I will be forced to take my Medicare patients off of the medication, even if it is working well for them. Since I do not want to do this, I ask that you consider including psychiatric medications within the Competitive Acquisition Program.

Sincerely,

Kathleen Potter MN, CS, ARNP
Founder & Director
Mountainside Mental Health

c.c. WASHINGTON STATE PSYCHIATRIC ASSOCIATION
E-Mail: wspa@sbims.com <mailto:wspa@sbims.com>

Submitter : Dr. Jeffrey Kaufman **Date:** 04/19/2005

Organization : American Association of Clinical Urology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Sirs: I am writing to you as the president-elect of the American Association of Clinical Urologists which represents almost 5,000 physicians throughout the country to comment on the proposed rules governing the Competitive Acquisition Program. We have many concerns with the form and rules that have been proposed. First, we are concerned that there is a considerable amount of overhead work and responsibility to be undertaken by the practicing physician that is not compensated for within the codes used for and reimbursement available for administering the drugs in question. While we understand that it is CMS' contention that the codes used for administrating these drugs provide enough compensation and that there will be no more work involved than that which is associated with current methods of acquiring and delivering the drugs, recognize that much of the current work reimbursement is included in whatever profit is derived from reimbursement for the drug costs themselves, not the payment for administering the drug.
The new program will cause us to order drugs one by one, much less efficient than the current method where we order in batches depending on our anticipated usage. We will be required to track the drug and its prescription number, work with vendors to insure that they are properly paid, intervene on behalf of the vendor whenever there is a denial for the drug or the patient fails to pay his copay or deductible and return unused drugs. These efforts are much more than those currently attached to simply administering the drug but there is no greater reimbursement for our time, risk and efforts.

Second, we are very concerned that this program, combined with the LCA policy of most carriers and intermediaries will result in vendors delivering drugs different than that which was ordered. This will create problems for both the physician as well as the patient who may have good reasons for wishing one drug rather than another even when those reasons are not sufficient to trigger the 'furnish as written' rules. Currently, the doctor can choose to supply whatever drug he agrees to with the patient even when paid less for the LCA alternative. With the CAP, doctors and patients lose that flexibility and freedom. Since not all drugs are equal (even when they are equally effective), this may lead some patients to refuse treatment which creates a major dilemna.

Third, why must there be a single enrollment period per year? Doctors should have the opportunity to join or leave the CAP throughout the year as their practice situation changes and the published ASP plus 6% rates vary. There is no reason that the vendors need to have doctors all locked into or out of their programs. The yearly contract does not provide efficiencies or allow for better planning for the vendors since each doctor's usage of drugs may vary widely throughout the year. Yet, limiting our opportunity to enroll to one 6 week period yearly requires each doctor to bet in advance on the risk of increased overhead costs of hassles (associated with the CAP program) offsetting the risk that the ASP rate will fall below his cost of acquisition. You are requiring America's physicians to make their bets once per year. The enrollment period should be altered to allow continuous selection. If the program is attractive, it will have sufficient enrollment. If the program is failing, it is unfair to rope doctors into it simply motivated out of fear that they will lose money staying in the current ASP based payment system.

Fourth, why must a doctor be either all in or all out of the CAP? Why can't a doctor choose to use the CAP for some drugs and not for others? I will continue these comments in another message. Thank you for allowing me to address these issues. Jeffrey Kaufman MD, FACS

Submitter : Dr. Jeffrey Kaufman **Date:** 04/19/2005

Organization : American Association of Clinical Urologists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Thank you for allowing me to continue my comments expressing the concerns of 5000 of America's urologists. Please view my first message concerning the increased overhead and responsibility this program creates for physicians without increased reimbursement and our concern that using LCA policies will cause patients to receive medications other than what they have chosen. Our further concerns involve patients who may not have fulfilled their financial obligations to make copayments or deductibles but who continue to require medications. Currently, doctors have the option to provide the medication even when they lose money on a compassionate basis. We are concerned that the vendors under the CAP program may not be so sympathetic and leave poor patients with no source of medications. Further, what real recourse does a doctor have when the vendor is performing poorly--either failing to provide drugs in a timely fashion or otherwise not meeting the patient's needs. We understand the program has mechanisms to allow us to resolve complaints but these are very time consuming for the doctor who does not receive any reimbursement and who has no direct power to force the vendor to comply with rules. We are very concerned that large vendors will abuse their positions. Next, we feel very strongly that the costs negotiated by these new large vendors should not be included in computations regarding ASP since the government program gives them enormous bargaining power not available to the rest of us and creates great jeopardy for those doctors who continue to receive reimbursement based on the ASP system. Similar to keeping VA hospital purchases out of the ASP computation, purchases thru the CAP program should not be considered. Next and very importantly, we feel that a physician advisory panel should be established for clinical input into this program similar to the Carrier Advisory Committees currently utilized by CMS for part B. Without physician input, there is a great opportunity for this program to cause harm to our patients. Next, we are concerned about how the geographic regions will be established, especially if two states are put together under one vendor when one state currently pays based on LCA policy and the other does not--which policy will dictate payment for the drugs and determine which drug is supplied to the ordering physician. Because of these and other concerns, we strongly request that this program be slowly phased in over various regions to allow us to identify and correct problems as they arise. If the CAP program is instituted over the whole country and over many different specialties at the same time, there is great potential for poor performance. At the present, this program is not attractive to the great majority of doctors but we feel the program has the potential to force many doctors into either accepting it or denying access to care to their patients. Please insure that the program starts successfully and doesn't deny access to care for our patients. Thank you for this opportunity to comment on the proposed rules governing the CAP.

Jeffrey Kaufman MD, FACS
President elect, AACU

Submitter : Henriette Warren **Date:** 04/20/2005

Organization : Detroit Central City Community Mental Health

Category : Social Worker

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

Psychotropic medication for individuals with a severe and persistent mental illness including injectables. Recognition of the deveopment of new medications in the field.

GENERAL

GENERAL

I am writing in support of the inclusion of psychiatric medication in the implementation of CAP. This letter is written on behalf of the 50 professionals who are employed at Detroit Central City. We are an agency that provides services to over three thousand individuals who have been diagnosed with a severe and persistent mental illness. Many of these individuals have been recently hospitalized. These individuals often have numerous health concerns that can be exacerbated because of the lack of psychotropic treatment of their mental illness. By failing to include another means of procurement for medication these consumers are placed in greater risk. It is vital to insure that an individual is treated for all co-occurring illnesses in an integrated manner. Please do no ignore a class of medication in the implementation of the MMA.

Submitter : **Dr. Ruben Sierra** **Date: 04/20/2005**

Organization : **Columbia Basin Hematology Oncology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Columbia Basin Hematology Oncology cares for about 75-80% of the Medicare oncology patients in the region.Our area of referral is of about 300-450,000 people.
In the past I have participated in a very similar program with an HMO.It was an absolute disaster.Drugs often were not on time.My nurse spent large amount of time trying to get the correct drugs.Often we had to use our own inventory to treat the patients and re-stock it with the drugs when arrived.
This are only some of my personal experiense with such a program.
At present time we are struggling with Medicare.One more cut,imposition,burocracy,will be enough for us to stop participating in the program.
I know the quality of the drugs that we give.I know how and were mixed,by whom.We have a very strong quality assurance program.We are fully responsible for all that.If we choose to participate,we will be responsible for the safety of our patients,but we will not have control of a very importan detal,THE DRUGS USED.The liability,time,paperwor,headhaces will not be worthwide.
Thank you for listening.

Ruben Sierra,MD
Business Partner,
CBHO
7350 W. Deschutes
Kennewick,WA 99336

Submitter : **Ms. Sheila Amdur** **Date: 04/20/2005**

Organization : **NAMI-CT**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

We are very concerned about assuring ready access to needed prescription medications for people with serious mental illnesses. In particular, we urge CMS to include all psychiatric drugs under the new rules implementing the Competitive Acquisition Program. Furthermore, we urge CMS to include psychiatric drugs in Phase I of CAP, so that current barriers to access will be addressed.

In the categories of drugs that vendors will provide to physicians, we urge CMS to create a category that includes psychiatric drugs, including long-acting injectable antipsychotics. We are also concerned that CMS address how vendors should handle uncollectible copays and other reimbursement issues, so that an individual's therapy is not interrupted.

Thank you.

Sheila B. Amdur
Public Policy Chair, Board of Directors
National Alliance for the Mentally Ill, Connecticut
30 Jordan Lane
Wethersfield, CT 06109

Submitter : **Ms. Janice Jordan** **Date: 04/18/2005**

Organization : **Mid-South Cancer Center**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

REFERENCE: CMS-1325-P I am very concerned with the potential problems associated with the competitive acquisition program for drugs. First, there is the problem of the timing of ordering and receiving the drug for the patient. Due to changes in schedules, patient cancellations, etc, it will be very difficult to have the drug in our office at the exact right time needed for the patient. Also, it will be very confusing to the patient to deal with payment, Medicare claims processing, etc with an outside vendor - and not their physician. And, the issue of BAD DEBT has not been addressed at all. Oncologists deal with the situation all the time and have to cover those times when patients are unable to pay timely - or at all. How will this work with this program ? If the patient does not pay the vendor - will his drug be shipped to the physician office for the next scheduled visit ? Then, there is the issues concerning ASP and the once a year election for this program. With the change to the ASP program, there has been much misunderstanding of how ASP is calculated and how we, as a physician practice, are going to continue to treat our patients with declining reimbursement. If you have to elect the CAP program once a year, it hinders your ability to make the necessary changes in the year to survive. In summary, it seems that with all the issues we already have at hand with declining reimbursement, now is NOT the time to implement the competitive acquisition program with all it's potential problems. Cancer Care is in a CRISIS and we need to address our existing problems first and hold off on any type program such as the CAP, until we have addressed the other critical issues. Until the "bad debt" issue is resolved - we CAN"T go to the competitive acquisition program anyway because patient treatment would be affected.

Submitter : Dr. Taral Patel **Date:** 04/20/2005

Organization : Mid Ohio Onc/Hem Inc

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

We are extremely concerned that CAP introduces a middleman between the sacred patient/physician relationship, because it will be the vendor dealing with the patient for the Medicare co-insurance drug payment. Patients who cannot afford to pay the co-insurance will most likely be sent by the vendor to a collection agency or forced to pay ?up front.? This removes the current ?safety net? that community cancer clinics provide to their patients who have financial difficulties.

On a very practical level, CMS has not addressed the bad debt that community cancer clinics carry relating to co-insurance payments that are not covered. No commercial vendor is going to float these payments as community cancer clinics are forced to do on behalf of their patients.

Submitter : **Dr. Michael McCleod** **Date: 04/20/2005**

Organization : **Florida Cancer Specialists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

4-20-2005
My concerns with CAP are that you are locked into the drug vendor you chose for an entire year, regardless of vendor adherence to quality, delivery, etc. Patients will be inconvenienced and have to return for treatment (new or switched) because drugs will have to be ordered. Multiple vendors may be supplying drugs that go into a treatment regimen, thus creating a logistical nightmare. Community cancer clinics currently maintain one drug inventory. CAP will produce multiple inventories, possible individual patient inventories. Aspects of CAP appear to violate pharmacy laws.
CAP will produce additional administrative burden, which we doubt will be compensated for by Medicare.

I am extremely concerned that CAP introduces a middleman between the patient/physician relationship, because it will be the vendor dealing with the patient for the Medicare co-insurance drug payment. Patients who cannot afford to pay the co-insurance will most likely be sent by the vendor to a collection agency or forced to pay ?up front.? This removes the current ?safety net? that community cancer clinics provide to their patients who have financial difficulties. This also introduces a new area of liability for the oncologist in that we are still responsible for the drugs that we administer even though we would have no control over storage, delivery, and quality, as well as source of acquisition.

Therefore, this seems to be a very cumbersome, impractical system for providing chemotherapy drugs, which will be an inconvenience and financial burden to our Medicare patients in addition to the possibility of safety issues related to this proposed method of providing chemotherapy drugs.

Submitter : Mr. Charles I. Busack **Date:** 04/20/2005

Organization : Center for Urologic Care of Berks County

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

As the Administrator for a urology group of 7 physicians, I would like to express my concerns over the proposed CAP plan.

1) It is unfair to make physicians have an annual election for the CAP program when injectable drug prices are updated quarterly. The election period should also be quarterly.

2) We have hundreds of Medicare patients who receive various injectable drugs. Currently we are able to buy our drugs in bulk - under this plan we would be receiving drugs individually. The added administrative burden will be incredible. It will add at least an hour a week (per patient) of administrative time to order, manage, and place in inventory the shipments of drugs. The administration code will not adequately reimburse us for this extra burden.

3) I have major concerns regarding the very limited opt out provision once your are in the program. It is my understanding that you can only opt out if there are two (or more) drugs which share the same HCPCS code and the physician wants to use drug X and the vendor is only supplying drug Y. But the physician also needs to prove a medical necessity for why drug Y should be used. How will that proces be managed? How strict will the opt out rules be?

4) Another major concern is will a vendor be able to implement the Least Costly Alternative (LCA)? For example, vendor inform us that they will only supply Zoladex not Lupron (even though they have two different CPT codes)? How will we know if a vendor is going to do this? Will we know this ahead of time?

5) These drug vendors will be able to gain such a buying power that if they can buy the drugs at the lowest possible price that will lead to the ASP price being lowered and will adversely impact the practices who opted out. This is another reason why the election should NOT be for a year but for a quarter.

6) The CAP plan seems more in favor of the vendors than physicians. For example there is no physician advisory board with the designated carrier (like there is with our local carrier). Also the vendors can take physicians to a Medicare hearing officer if they have a problem with a physician; however a physician cannot take a vendor to a hearing officer. If a vendor sends the wrong drug, or ships a drug late or damaged, that impacts patient care. If a physician fails to help the vendor get paid on a drug, the vendor can still ultimately get paid.

Thank you for your consideration.

Charles I. Busack, MHA
Administrator

Submitter : **Ms. Tammie Jones** **Date: 04/20/2005**

Organization : **Horizon Oncology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1325-P-137-Attach-1.DOC

Tammie Jones
Horizon Oncology
1345 Unity Place, Ste 345
Lafayette, IN 47905

RE: Comments on the CAP proposal

April 20, 2005

Dear Sir or Madam:

There are several aspects of the CAP/MVI proposal jeopardizing the oncology patient's access to care. Very simply, CAP will introduce new hardships for both patients and doctors.

If elected, CAP allows for no emergency provisions, creates new claim filing burdens for the administrative staff in the oncology office, forces physicians to use a "vendor" established formulary to treat patients, mandates individual patient inventories, and locks a physician in to a vendor for one year unless the vendor ceases to do business. Rather than alleviating physician burden, CAP makes it worse. Emergency drugs are administered for many reasons and cannot always be anticipated by the physician—reactions, nausea and/or vomiting, cardiac episodes, etc. An individual patient inventory of drugs is impossible—in our office, we do not have the extra staff to accommodate such a demand. A vendor formulary limits the physician's clinical recommendation as some drugs may not be available through the vendor and the drug will not be obtainable due to the poor reimbursement option of billing Medicare direct—also, the physician will not have the option to change vendors for 1 year.

Allowing the CAP vendors to split treatment orders will create a virtual nightmare—I foresee vendors using this as an insurance policy for co-pay collection. If the patient cannot pay the co-insurance, the vendor might decide to delay or even cancel the remaining shipment of drug.

It must be understood that oncologists cannot operate under these circumstances; an oncology office has to be prepared at all times to handle different situations when administering chemotherapy as each patient is special. We cannot risk the patient's access by allowing CAP/MVI to take cancer care out of the hands of the physician and give it to a vendor.

Sincerely,
Tammie Jones

Submitter : Mrs. Linda Thornrose **Date:** 04/20/2005

Organization : Gainesville Hematology Oncology Associates

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

Submitter : **Mrs. Linda Thornrose** **Date: 04/20/2005**

Organization : **Gainesville Hematology Oncology Associates**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

CAP is bad medicine and bad economics. As a summary, it risks patient care, imposes extra costs and liability on community cancer clinics, and will cost Medicare more money.

We are extremely troubled that CAP will be implemented without any testing or analysis of what is a radical change in the cancer care drug delivery system. The current drug delivery system developed by community cancer care is a time-tested, proven system. It is extremely effective and efficient in providing treatment to Americans battling cancer. To substitute this proven delivery system with a concept that has not been tested is very dangerous.

Some specific concerns we have about CAP as currently structured are as follows:

You are locked into the drug vendor you chose for an entire year, regardless of vendor adherence to quality, delivery, etc.
Patients will be inconvenienced and have to return for treatment (new or switched) because drugs will have to be ordered.
Multiple vendors may be supplying drugs that go into a treatment regimen, thus creating a logistical nightmare.
Community cancer clinics currently maintain one drug inventory. CAP will produce multiple inventories, possible individual patient inventories.
Aspects of CAP appear to violate pharmacy laws.
CAP will produce additional administrative burden, which we doubt will be compensated for by Medicare.

We are extremely concerned that CAP introduces a middleman between the sacred patient/physician relationship, because it will be the vendor dealing with the patient for the Medicare co-insurance drug payment. Patients who cannot afford to pay the co-insurance will most likely be sent by the vendor to a collection agency or forced to pay ?up front.? This removes the current ?safety net? that community cancer clinics provide to their patients who have financial difficulties.

On a very practical level, CMS has not addressed the bad debt that community cancer clinics carry relating to co-insurance payments that are not covered. No commercial vendor is going to float these payments as community cancer clinics are forced to do on behalf of their patients.

Our office has tried this form of drug provision for our patients for a one year basis about 4-5 years ago and it was a nightmare. The standard of medicine is way below the standards of care in our practice. Adding such a complex layer (much more complicated than what we used in that experimental year)will waste tax-payer dollars with more bureaucracy leading to a large margin of error and waste, particularly due to 20-40% of patients conditions changing and causing a change in their treatment plans. I attended the 2005 Oncology Summit in Washington DC Monday. This forum was excellent with politicians, payers, pharma and physicians all in attendance to discuss the issues facing oncology patients today. As the discussion pertained to CAP the way it is currently written, all present agreed that it will not work for either the CAP vendors, physicians or patients. There are many flaws that must be addressed or it will never work. Please, I invite you to call or visit me, my and my honorable, dedicated physicians to listen to solutions to enable both Medicare and oncology practices to provide cost-effective, quality care for our mutual patients. This can be done simply and effectively. Please, listen to those of us in community oncology. Thank you for the opportunity to offer my comments on this very important issue.

Submitter : **Ms. Bernadette Setlik** **Date: 04/20/2005**

Organization : **Huron Medical Center Port Huron Michigan**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

The implementation of CAP with any testing or analysis to caner care delivery is very dangerous.

Introducing a middleman between the patient and physician for co-insurance removes the safety net that community cancer clinics provide to their patients who have financial difficulties.

Introducing multiple vendors will produce multiple inventories, possible individual patient inventories which oncology offices will undoubtedly not be compensated by Medicare.

CAP places patient's at risk, imposes extra costs and liability and in the long run cost Medicare more money.

Submitter : **Ms. Tammie Jones** **Date: 04/20/2005**

Organization : **Ms. Tammie Jones**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Reading the CAP provisions, I have repeatedly noticed that it has been presented in a way to make it appear to save burden on the physician; however, the opposite is true--the physician will still have to maintain an inventory of drugs to cover for emergency situations, last minute changes, etc. CAP doesn't eliminate a physician's inventory of drugs and therefore does not eliminate the cost associated with maintaining an inventory.

Submitter : Mrs. Judy Marshall **Date:** 04/20/2005

Organization : Southeast Georgia Hematology/Oncology Associates

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am the practice manager for this 3 physician medical oncology practice in rural South Georgia. I have a great many reservations with the proposed CAP program as I do not feel it is in the best interest of our patients. For one thing, we will be stuck with one vendor for a whole year regardless of the service or quality of service they provide. What happens when a patient shows up for treatment and b/c of blood counts, etc., cannot get their treatment for that day or if a different drug needs to be used, the patient will most likely have to return another day since that drug will have to be ordered. How do we maintain inventory? It seems that it will place even more of a burden on an already over-burdened staff with administrative issues of this sort. I really do not understand how the vendors are going to handle collection of the patient's portion if they are Medicare only as most of our patients currently do not have the ability to pay for that. It just seems as though there are many questions that still need to be answered before this program is rolled out. I firmly believe the physician's office is the entity that should order, maintain, and give the drug as the physician is accepting all the medical liability for doing exactly that. I hope enough time will be taken to thoroughly examine this program before implementing. Thank you for your time.

Submitter : **Ms. Elisabeth Kennedy** **Date: 04/20/2005**

Organization : **East Valley Oncology and Hematology Medical Group,**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

April 20, 2005

Center for Medicare and Medicaid Studies
Washington, DC

Via Internet

Re: Docket CMS-1325-P

Dear Sir/Madam:

I write to express my concern regarding the Competitive Acquisition Program (CAP) scheduled for implementation in January 2006 pursuant to the Medicare Modernization Act of 2004. As the administrator of a very busy five MD oncology/hematology practice treating over fifty patients daily in the Burbank and Sherman Oaks suburbs of Los Angeles, I am frightened by the lack of foresight that has gone into this proposal. The problems, in order of importance are:

1. It appears that practices who implement CAP will be forced to keep patient specific inventories. This is not only impractical for a practice our size, but impossible. The administration, space and staffing required to implement this for two-hundred fifty individual patients per week is staggering. Presently we use technology to help manage the inventory and we have inventory delivered daily based on practice wide utilization. We do not have the space to store more than one treatment at a time per patient. We do not have the staff to inventory and dispense patient specific prescriptions. Additionally, 20 to 30% of all treatments are missed by patients who are either not responding or are admitted to the hospital for one reason or another. Either scenario would result in wasted drug the $$ of which would vastly exceed any possible savings on price reductions achieved by implementing such a program. We have tried such a program with one of our regional HMOs (which sent us no more than two treatment patients per week) and they terminated it because the costs were so high. From this perspective alone, the CAP program seems a foolhardy and shortsighted undertaking.

2. Practices can only choose one vendor per year. We frequently must shop individual products for patients because our primary vendor cannot access them or has run out of their supply and there will be a delay getting additional drug from the manufacturer. This practice would be prohibited and patients forced to suffer the consequences of the poorly designed program.

3. CAP vendors will be allowed to establish formularies. So for instance, the vendor will choose which anti-emetic to supply based on its acquisition price. While this may work for 80% of patients, 20% will not respond to this anti-emetic and will need access to another drug. As impossible as it would be to administer this program, worse would be to administer both this and the more traditional system simultaneously. Many patients will not have access to the medicines they respond to best.

4. The purpose of this program - as I originally understood it - was to remove the burden of billing and collecting for the drugs from oncologists. However, based on the current proposed rule, the practice will not only have a vastly more complex order and inventory system, but it still required to bill Medicare AND provide the data to the Vendor, help THEM collect applicable co-payments and deductibles and agree to provide documentation and assistance in any required appeals process. All for no reimbursement whatsoever. In short, CMS has dramatically increased the cost to the practice and removed any sort of reimbursement.

I imagine the majority of the oncology community has communicated similar comments to CMS and I urge you to heed them and recraft this plan. It is unworkable in its present configuration and we will not participate.

Thank you for your consideration and please contact me directly should you have questions or seek additional input.

Sincere regards,

Elisabeth Kennedy-Lesser
Administrator
East Valley Hematology and Oncology Medical Group, Inc.
(310)568-9595

Submitter : **Ms. Linda Yager** **Date: 04/20/2005**

Organization : **self**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

As a caregiver of a cancer 'parent',I strongly oppose CMS implementing CAP. My mother's health changed frequently throughout her breat cancer treatments. Often times her treatment was held because she was too sick. Mom's oncologist states that he will go out of business if he has to comply with the administrative costs associated with CAP.

Please keep the delivery of chemotherapy treatments in the physician office. The caring envirnoment and access to knowledgable physicans and nurses is what kept our mom going throughout her 8 months of treatment.

Linda Yager

Submitter : Ms. Deborah Gonzalez **Date:** 04/20/2005

Organization : St. Louis Hematology Oncology Specialists

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please remember that we are dealing with real people who may or may not receive their treatments in a timely fashion due to coordination of drug shipment/availability, the patient's lab values and disease state, and availability of transportation to the office. When the patient can not be treated per the chemo protocol it changes the efficacy of the treatment and thus can bring into play risk management questions such as ,"Who is responsible if the patient fails chemotherapy or is hospitalized due to untimely treatment?"

If the patient dies or their treatment has to be changed due to disease progression,what happens to the drug if it is already in the office? In such scenarios, I have had speciality pharmacies tell me to "throw the drug in the trash" because it can not be returned to the vendor and it can not be used on another patient because it was already charged to the originally intended patient. If it could be used on another patient and was indeed shipped back to the vendor to be shipped out again to another office, who would guarentee the potency of the drug? Many oncology drugs are temperature and light sensitive and can be compromised during shipping. This could also happen if an incorrect dose was shipped in error.

I also understand that the medical practice could still be responsible for assuring that the vendor is paid by Medicare for any drugs shipped to the practice by providing assistance with claim appeals and review. This would be labor intensive and not productive from this stand point.

In short, the CAP Program will promote a poor quality of care, thus incurring more hospitalized patients. It will promote a waste of resources, not only product waste, but manpower hours wasted.

ASP was developed to help keep cost down and it is the only system that ,in fact, rewards drug companies for keeping their prices high.

Submitter : Dr. Frederic Holcomb **Date:** 04/20/2005

Organization : Shoals Urological Assoc

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am concerned over a cumberson program to be initated for prostate ca patients. There is no efficient way to administer these drugs in an orderly fashion with the proposed rules. Also I have a concern as to the extra administrative burdens that we will incur for no compensation. Also the risks we take with no assurances for our own financial status as related to these CAPs is very concerning. There is no doubt that the proposed rules will force me to have my good patients get there treatment in another venue which is very limited in our area. I do not intend to allow the government to ruin my remaining years of practice and place me in a financial strain to continue to practice good urology and provide good jobs for many people. There are a lot of ways to remedy this problem without this inefficient and onerous proposal.

Submitter : Dr. Willliam A Biermann **Date:** 04/20/2005

Organization : Cantor Biermann Fellin Associates

Category : Physician

Issue Areas/Comments

1-15

Overview of the CAP

This system is very likely to have a dangerous impact upon the patients that community Oncologists treat. We have already seen a case of dilution of drugs to increase the profits of a pharmacist. My major concern is that the system will place infusion companies between ourselves and the patient. Many companies are already looking to ways to capture patients for chemotherapy. When we treat our patients in the office we are present and able to evaluate their symptoms on site. The idea of having an intermediary deliver the drugs to us also is likely to be quite costly for the system. We often will change doses or drugs based on decisions that are made at the time of a visit. Those changes could cost the system a great deal of waste.
The most distrubing part of the proposal is that it flies in the face of expert opinion like Berwick. There is no intent to improve quality in any of the changes suggested. Studies ata Harvard school of business suggest that cost containment for its own sake is foolish and costly. I would suggest that CMS work with the Oncology community to develop disease management programs that would save money. We should try to understand why 35% of stage IV lung cancer in the Philadelphia region receive chemotherapy within 30 days of death.(IBC data)I suspect that for a few it is greed. For some physicians, it is more cost efficient under medicare to push chemo rather than talke realistically with the patient and family. For some physicians it is to not lose the patient to a cancer center where off protocol treatment is given to 80% of the cases.
The system needs repair, but done with some thought for the unintended consequences that are not seen on a balance sheet.

Submitter : Ms. Carol Gillihan **Date:** 04/20/2005

Organization : Highline West Seattle Mental Health

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

The buy and bill procedure for Risperdal Consta has been very complicated and time consuming for our agency. This results in decreased access for our patients. We are requesting that psychiatric medications fall under the Medicare Part D program. January 1, 2006 as it would be best for patient care.

Thanks for your consideration,

Carol Gillihan RN-C, MSW
Lead Nurse

Submitter : Dr. Glenn Tisman

Organization : Dr. Glenn Tisman

Category : Physician

Date: 04/21/2005

Issue Areas/Comments

GENERAL

GENERAL

Competitive Acquisition of Outpatient Drugs and Biologicals is a plan that has flaws.

Scenario#1. I order drugs necessary for chemotherapy for a patient. They come in and are placed in his bin for use by him alone. The protocol says give drug A,B,C together every two weeks. After two courses the patient cannot tolerate or has liver function problems and cannot use drug C. I must return drug C. But the day of discovery of the liver problem at 7 pm I can substitute drug D but I don't have drug D today so the patient has to return when drug D is ordered and delivered. Unfortunately its efficacy when given with drugs A and B delayed (by 1-2 days) is less effective (decreasing dose-density) or given by itself as a delayed single agent is not as good.

Scenario # 2. The patient cannot afford the drug. Does the vendor withhold the drug from the patient? But I am the responsible party.

Scenario # 3. I need an emergency supply of drug STAT. How do I get it?

Scenario #4. I ordered an entire course of chemotherapy for a patient. I stock the drugs in his bin. The patient goes to another physician or is admitted to hospital for emergency and receives hospital drug for completion of therapy. What do I do with the remaining drug? Who pays my worker for keeping track of spent or unspent drug.

Scenario #5. Who pays for the stocking clerk I will have to hire to keep track of ordering, canceling orders, and returning unused drug.

Scenario #6. Sorry Dr. that drug is not on our formulary. This will force us to use second choice drugs.

I suspect that if I thought about this more I could come up with many more scenarios that would reveal inconvenience for severely sick patients. There is no doubt that drug delays will decrease dose-density of protocols and this will compromise cure.

Submitter : **Salvatore Del Prete** **Date: 04/21/2005**

Organization : **Salvatore Del Prete**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

The CAP program is poorly thought out, by those uninvolved in the care of cancer patients, and will make it impossible for outpatient oncology to continue to be practiced with the patient's best interest in mind. TO force oncologists to use ONE vendor all year, does not give them to ability to demand, during the year, good service. To force doctors to order drugs for particular patients is forcing them to maintain individual inventories which simply is not possible within the confines of most practice pharmacy areas. The fact is that inventories of this sort are not practical, and are wasteful. It is not infrequent that drugs are changed at a moments notice; new drugs added to ongoing programs; new supportive care drugs might be needed. If a pt comes to me with intractable nausea and vomiting one day after gettting cisplatin, I guess I tell her to come back tomorrow as I need to ORDER THE DRUG thanks to COngressman SHays, or Congresswoman Johnson. Is that the deal?? Or do I admit her to the inpatient service at greater expense and much less bother to myself and my staff?? Instead of seeking to lower costs where the TRUE costs are: THE PHARMACEUTICAL industry, the US GOVT is trying to squeeze blood out of the stone that is oncology and CANCER patients! Has ANYONE actually tried to use this system or is it a Descarte thought experiment? Should I have my patients sign informed consent forms for this experimentation?

This year already we admit EVERY PATIENT WHO DOES NOT HAVE THE 20% copay. Next year I can see where most if not allof our medicare patients will be getting chemo in our hosp. inpatient dept.

Nice work. Since most Democrats didn't vote for this bill in the first place, I guess, though a Republican, I know who to support next time around...and so do our thousands of patients in CT.